MARCELA PONZIO PINTO E SILVA

IMPACTO DE UM PROGRAMA DE REABILITAÇÃO EM MULHERES SUBMETIDAS À BIÓPSIA DO LINFONODO SENTINELA OU LINFADENECTOMIA AXILAR POR CÂNCER DE MAMA INICIAL

Tese de Doutorado

ORIENTADORA: Profª. Drª. SOPHIE FRANÇOISE MAURICETTE DERCHAIN
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Tese de Doutorado apresentada à Pós-Graduação da Faculdade de Ciências Médicas da Universidade Estadual de Campinas para obtenção do Título de Doutor em Tocoginecologia, área de Ciências Biomédicas

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Dedico este trabalho...

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meus pais e irmãos,

minhas amigas da equipe de fisioterapia.

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Sumário

Símbolos, Siglas e Abreviaturas

ALND – *Axillary Lymph Node Dissection*

AWS – *Axillary Web Syndrome*

BCS – *Breast Cancer Subscale*

BLS – Biópsia do Linfonodo Sentinela

BMI – *Body Mass Index*

CAISM – Centro de Atenção Integral à Saúde da Mulher

EWB – *Emotional Well-Being*

FACIT – *Functional Assessment of Chronic Illness Therapy*

FACT-B – *Functional Assessment of Cancer Therapy- Breast*

FACT-G – *Functional Assessment of Cancer Therapy- General*

FWB – *Functional Well-being*

INCA – Instituto Nacional do Câncer

LA – Linfadenectomia Axilar

LS – Linfonodo Sentinela

P – Probabilidade da amostra

PWB – *Physical Well-being*

QoL – *Quality of Life*

QLQ-C30 – *Cancer Quality of Life Questionaire*

OMS – Organização Mundial da Saúde

QV – Qualidade de Vida

ROM – *Range of Motion*

SNB – *Sentinel Node Biopsy*

SWB – *Social/Family Well-being*

TOI – *Trial Outcome Index*

UNICAMP – Universidade Estadual de Campinas

WHO – World Health Organization

Resumo

OBJETIVO: o objetivo deste estudo clínico foi avaliar a qualidade de vida (QV) e a recuperação físico-funcional das mulheres com câncer de mama inicial submetidas à biópsia do linfonodo sentinela (BLS) ou à linfadenectomia axilar (LA) e investigar os efeitos de um programa de reabilitação. **SUJEITOS E MÉTODOS**: um estudo clínico longitudinal foi conduzido usando três grupos de pacientes. Os participantes de estudo foram mulheres tratadas por câncer de mama primário estádios I e II no Centro de Atenção Integral à Saúde da Mulher da Universidade Estadual de Campinas (UNICAMP). Recrutamos mulheres que realizaram quadrantectomia, sem evidências de metástases a distancia e nenhuma malignidade prévia. Essas mulheres assinaram um termo de consentimento informado, anteriormente aprovado pelo Comitê de Ética e Pesquisa, estabelecido na Declaração de Helsinque. As mulheres recrutadas iniciaram a pesquisa em maio de 2006 e terminaram em dezembro de 2007. Um dia antes da cirurgia, as 89 mulheres incluídas no estudo foram examinadas e responderam a uma entrevista sobre características demográficas, clínicas e sociais. Segundo o protocolo de serviço, 58 mulheres realizaram a BLS e 31 mulheres foram submetidas à LA. Trinta mulheres que sofreram BLS foram alocadas para um programa de reabilitação pós-operatório, de agora em diante denominado "BLS com reabilitação" e 28 pacientes foram selecionadas para a continuação clínica, de agora em diante denominada "BLS sem reabilitação". Todas

as mulheres que sofreram LA participaram do programa de reabilitação. Todas as participantes do estudo foram avaliadas através de exame físico e completaram um questionário de QV trinta dias e seis meses após a cirurgia. **RESULTADOS**: ***ARTIGO 1*** As mulheres que realizaram LA tiveram uma QV melhor dentro de 30 dias após a cirurgia no FACT-B (p=0.0117); FACT-G (p=0,0425); TOI (p=0,0104); EWB (p=0,0003) e BCS (p=0,001). Esta melhora permaneceu significativa seis meses após a cirurgia no bem-estar emocional (p=0.0204). As mulheres que realizaram BLS e participaram do grupo de reabilitação tiveram uma QV melhor somente no bem-estar emocional seis meses após a cirurgia (p=0,0334) e no grupo sem reabilitação esta melhora foi significativa somente 30 dias (p=0,0386). Comparando as médias gerais do FACT-B e suas subescalas não observamos qualquer diferença significativa na QV entre os diversos grupos. A subescala do bem-estar emocional melhorou significativamente (p=0.0041) com o tempo para todos os grupos. ***ARTIGO 2*** No grupo de LA houve redução na flexão e abdução da amplitude de movimento do ombro durante todo o seguimento. Não encontramos qualquer déficit significativo do movimento do ombro em mulheres que sofrem a BLS. Houve dois casos de *Axillary Web Syndrome* (AWS) e nenhum aumento em medidas da circunferência do membro ipsilateral à cirurgia. **CONCLUSÃO**: Um programa de reabilitação, incluindo a fisioterapia, é essencial no cuidado pós-operatório de mulheres que sofreram LA. Apoiamos a teoria de que BLS se associa com uma baixa morbidez do braço em seguimento a curto prazo, porém não nos permitem excluir as mulheres submetidas à BLS de um programa de reabilitação.

Palavras-chave: qualidade de vida, avaliação, questionário, reabilitação, câncer

Summary

OBJECTIVE: The aim of this clinical study was to evaluate quality of life (QoL) and evaluate shoulder range of motion, lymphedema and axillary web syndrome in early-stage breast cancer patients and to investigate the effects of a comprehensive rehabilitation program comparing women undergoing sentinel node biopsy (SNB) versus complete axillary lymph node dissection (ALND). **SUBJECTS AND METHODS:** A longitudinal clinical study was conducted using three groups of patients. Study participants were women treated for stages I and early II primary breast cancer at the Women's Integral Health Care Center *University of Campinas* – UNICAMP. We recruited women undergoing quadrantectomy or simple mastectomy for local surgical treatment, who had no evidence of distant metastases and no prior malignancy. These women signed an informed consent form previously approved by the hospital ethics revision board, established in the Helsinki Declaration (World Medical Association, 1996). Patient recruitment began in May 2006 and ended in December 2007. On the day before surgery, all 89 women included in the study were examined and responded to an interview about clinical and social demographic characteristics. According to a standardized service protocol, 58 women were found clinically fit to undergo SNB only and 31 underwent quadrantectomy with ALND. Thirty women who underwent SNB were randomly allocated to a comprehensive postoperative rehabilitation program; from now on named "SNB with rehabilitation"

and the remaining 28 patients were selected for clinical follow-up, from now on named "SNB without rehabilitation". All women who underwent ALND engaged in the rehabilitation program. The SNB group without rehabilitation was scheduled for physical examination and asked to complete a questionnaire at 30 days after surgery. **RESULTS**: *ARTICLE 1-* Women undergoing ALND had a better QoL within 30 days of surgery on the FACT-B (p=0.0117); FACT-G (p=0.0425); TOI (p=0.0104); EWB (p=0.0003) and BCS (p=0.001). This improvement remained significant 6 months after surgery on the EWB subscale (p=0.0204). On the other hand, women undergoing BLS had a better QoL only on the EWB subscale, which was significant 6 months after surgery in the group with rehabilitation (p=0.0334) and 30 days after surgery in the group without rehabilitation (p=0.0386). ARTICLE 2- Regarding shoulder ROM, in the ALND group there were significant decreases in flexion deficits measuring and in abduction deficits measuring during the follow-up. We found no movement deficit in the SNB groups throughout the study. There were only two cases of AWS and only a slight increase in circumference measurements the upper limb ipsilateral to surgery. **CONCLUSION**: The rehabilitation program, including the physiotherapy, is essential in the postoperative care of women who undergoing ALND. This study supports the theory that breast cancer patients undergoing BLS associates with a low morbidity of the arm in a short term follow-up, however they do not allow us to exclude the women undergone to the BLS from the rehabilitation program. Regarding SNB, all women presented a significant improvement in the emotional well being, unrelated to the rehabilitation program attendance.

Key words: quality of life, assessment, questionnaire, rehabilitation, cancer

1. Introdução

O câncer de mama é o segundo tipo de câncer mais freqüente no mundo e o primeiro entre as mulheres (INCA, 2008). Apesar da alta incidência, tem-se observado um aumento na sobrevida destas mulheres, que pode estar relacionado com melhor tecnologia de imagens para rastreamento e detecção da doença em estágios iniciais, com diminuição de mulheres com metástases axilares e para outros órgãos. Também estão associados a novas e mais efetivas abordagens para seu tratamento (Naik et al., 2004; Smith et al., 2004; Turner et al., 2004).

Na abordagem apropriada da doença maligna da mama, a remoção cirúrgica e o exame histopatológico dos linfonodos axilares ainda permanecem como padrão de avaliação (Soni e Spillane, 2005). O estadiamento axilar é considerado o principal indicador de prognóstico e determinante na terapia sistêmica adjuvante. Entretanto, a dissecção dos linfonodos axilares pode resultar em morbidades do membro superior e lado afetado, restrição da mobilidade do braço, formação de seroma, fraqueza do braço, rigidez, disfunções sensoriais, Axillary Web Syndrome (AWS), dor, e linfedema, podendo atingir de 7% a 37% das mulheres (Soni e Spillane, 2005). Essas complicações são importantes causas de estresse emocional e

prejuízo funcional que poderão interferir na recuperação e qualidade de vida (QV) de mulheres operadas por câncer de mama. Por estes motivos, a extensão ideal da dissecção cirúrgica da axila torna-se um dos tópicos mais debatidos na assistência oncológica atual (Barranger et al., 2005).

Neste contexto, a biópsia do linfonodo sentinela (BLS) é uma nova e eficiente modalidade terapêutica, introduzida por Krag et al. (1993) e Giuliano et al. (1994) no tratamento por câncer de mama. Tem como objetivo evitar a dissecção completa e sistemática da axila em mulheres com câncer de mama inicial, mantendo o estadiamento precoce com diminuição da morbidade (Burak et al., 2002; Schijven et al., 2003; Leidenius et al., 2005; Mansel et al., 2006; Rietman et al., 2006; Schulze et al., 2006). A BLS é hoje uma prática rotineira em vários dos principais centros oncológicos do mundo por ser de execução simples e menos invasiva que a linfadenectomia axilar (LA) (Dubernard et al., 2004; Kanter et al., 2006; Wilke et al., 2006). A técnica identifica um ou mais linfonodos - os *chamados linfonodos sentinela (LS)* - localizados em mais de 95% dos casos no nível I da axila; podem ocorrer, entretanto, em até 5% dos casos, na cadeia da mamária interna. *Os LS* são os primeiros para os quais ocorre a drenagem linfática e podem predizer se o câncer está localizado na mama ou já atingiu outra região. Caso o resultado da biópsia seja negativo, a dissecção linfonodal poderá ser evitada com segurança para a paciente (Bass et al., 1999, Schrenk el al., 2000; Soni e Spillane, 2005).

As técnicas mais estudadas na identificação dos LSs utilizam enxofre coloidal marcado com tecnécio e/ou *isossulfan blue dye* nos Estados Unidos e Albumina marcada com tecnécio e/ou *patent blue dye* na Europa. (Gordon et al., 2002).

Na maioria dos estudos, a técnica da BLS apresenta menor morbidade quando comparada com a da LA, sem comprometer o controle regional da doença (Burak et al., 2002; Schijven et al., 2003; Leidenius et al., 2005; Mansel et al., 2006; Rietman et al., 2006; Schulze et al; 2006). Complicações como restrição de movimentos do ombro, dor, alteração da sensibilidade, da força muscular e fadiga poderiam ser evitadas com a utilização da técnica da BLS, podendo até diminuir a necessidade do acompanhamento fisioterapêutico em longo prazo (Schrenk et al., 2000; Burak et al., 2002; Schijeven et al., 2003; Fleissig et al., 2006).

Está claro que embora a BLS seja uma técnica menos agressiva, não está isenta de complicações que podem aparecer em conseqüência do inevitável trauma tecidual, da extensão da cirurgia axilar e da habilidade do cirurgião (Krynyckyi e Kim, 2004; Barranger et al., 2005).

O termo QV, segundo a Organização Mundial da Saúde (OMS), é definido como a percepção do indivíduo, tanto de sua posição na vida, no contexto da cultura e nos sistemas de valores nos quais se insere, como em relação aos seus objetivos, expectativas, padrões e preocupações. Porém, é um amplo conceito de classificação, afetado de modo complexo pela saúde física do indivíduo, pelo seu estado psicológico, por suas relações sociais, por seu nível de independência e pelas suas relações com as características mais relevantes do seu meio ambiente. Envolve fatores relacionados à saúde (bem-estar físico, psicológico, emocional e mental) e não relacionados à saúde (família, ambiente) (WHO, 1998).

Avaliar a QV passou a ser um componente expressivo da estratégia global no tratamento de doenças (Fleck et al., 2000). Atualmente é um parâmetro de avaliação que norteia decisões quanto a melhor distribuição de recursos dentro do sistema de saúde. Além disso, permite, através da individualização da assistência, que aspectos não observados rotineiramente pelo médico e muitas vezes não expostos pela paciente, possam ser trabalhados com maior ênfase. Por este motivo existe crescente interesse em transformar a QV em uma medida quantitativa que possa ser usada em ensaios clínicos e modelos econômicos e que os resultados obtidos possam ser comparados entre diversas populações e diferentes disfunções (Ciconelli, 1999).

Em mulheres operadas por câncer de mama, a percepção da QV pode ser influenciada também por alterações físico-funcionais, como diminuição da amplitude de movimento, fadiga, linfedema, dor e perda da imagem corporal em decorrência da perda da mama ou parte dela (Rietmam et al., 2006). Da mesma forma, as alterações psicossociais, como a mudança do senso de feminilidade e a diminuição da sensação de atração, também podem alterar de maneira negativa a QV (Rubin et al., 2003). Mediante todas estas possíveis complicações torna-se desejável a intervenção de uma equipe multidisciplinar para reabilitação no período de pós-operatório (Rubin et al., 2003; Cho et al., 2006).

Os programas de reabilitação surgiram tanto pelo grande número de mulheres acometidas por câncer de mama quanto pela necessidade de identificar e manejar melhor as complicações dos tratamentos. Em 1976, através da orientação da *American Cancer Society*, foi criado no *Memorial Sloan-Kettering Cancer*

Center, em Nova Iorque – Estados Unidos da América (EUA) -, um programa de reabilitação composto de orientações sobre a doença, exercícios, discussões e terapias de grupo, conduzido por enfermeiros, fisioterapeutas e voluntários (Winick e Robbins, 1976). Na década de 80, outros serviços em todo o mundo passaram a incluir programas de reabilitação multidisciplinar, voltada principalmente para os cuidados pós-operatórios de mulheres nos diferentes estágios do câncer de mama. Os programas de reabilitação oferecem informações e orientações referentes a exercícios, movimentação do braço, higiene, cuidados com a ferida cirúrgica e cicatrização, direitos sociais, aspectos sociais e emocionais (Rubin et al., 2003; Sachs et al., 1980; Sachs et al., 1981).

Nesta equipe multidisciplinar os profissionais de fisioterapia intervêm na reabilitação física, prevenindo complicações como restrição na amplitude de movimento do ombro, dor e linfedema, promovendo adequada recuperação funcional e contribuindo para proporcionar efeitos positivos sobre a QV (Silva et al., 2004; Valenti et al., 2008). A intervenção fisioterapêutica se faz, essencialmente, através dos exercícios e alongamentos que podem ser realizados em grupo ou até mesmo individualmente. Estes exercícios têm o intuito de promover uma boa amplitude de movimento, evitar aderências, melhorar a dor e prevenir o linfedema; além disso, contribuem para a melhora da postura e consciência corporal, que podem ser alteradas em decorrência da cirurgia. As orientações relacionadas aos cuidados com o membro superior homolateral à cirurgia para evitar infecções, inflamações e possivelmente linfedema, são também fundamentais durante o acompanhamento

fisioterapêutico (Silva et al., 2004; Cho et al., 2006; De Rezende et al., 2006b; Valenti et al., 2008).

Além dos sintomas físico-funcionais, os aspectos psicossociais, familiares, sexuais e de trabalho também devem ser investigados e abordados por influenciarem fortemente a vida destas mulheres, e a forma como aprendem a suportar os inconvenientes da doença e seu tratamento (Gordon et al., 2005; Cho et al., 2006). A individualização da assistência permite que aspectos não observados rotineiramente pelo médico, e muitas vezes não expostos pela paciente, possam ser trabalhados com maior ênfase apresentando melhores resultados. No Serviço de Mastologia do Centro de Atenção Integral à Saúde da Mulher (Caism) da Universidade Estadual de Campinas (UNICAMP), desde seu início, este tipo de conceito é abordado com excelentes resultados (Silva et al., 2004; De Rezende et al., 2005).

Desde 1979, para atender às variadas necessidades da paciente submetida à mastectomia, o Departamento de Ginecologia e Obstetrícia da UNICAMP promoveu a organização de uma equipe multidisciplinar de reabilitação. Essa equipe incluía a participação de vários profissionais interessados na problemática do câncer de mama, incluindo ginecologistas do Ambulatório de Mama, um oncologista, um fisiatra, uma fisioterapeuta, uma psicóloga, uma assistente social, e um grupo de voluntárias do "Programa Alcançar a Recuperação". Este último baseado no programa "Reach to Recovery", adotado pela American Cancer Society, criado por Terese Lasser em 1952, foi introduzido e adaptado neste meio por Helga Flatauer, voluntária do Hospital Israelita Albert Einstein. O programa "Alcançar a Recuperação" funcionava através de voluntárias "visitadoras" cuidadosamente

selecionadas, que se adaptaram com sucesso à sua própria cirurgia e que estavam aptas a auxiliar as pacientes a se reencontrar em suas necessidades físicas, psicológicas, e estéticas, transmitindo apoio moral nos difíceis períodos do pré e pós-operatório imediato. O programa de reabilitação global começava no período pré-operatório e se estendia até a alta hospitalar, quando as pacientes eram encaminhadas ao Ambulatório de mama para seguimento e conduzidas ao setor de fisioterapia com a equipe multidisciplinar (De Campos, 1984). Neste mesmo período surgiu o "grupo de apoio", a partir de encontros e considerações práticas de experiências vivenciadas das mulheres operadas por câncer de mama. Os atendimentos eram iniciados após a cirurgia e alta hospitalar e o grupo reunia-se semanalmente em sessões de duas horas, com no máximo dez pessoas. No ano de 1980, 37 pacientes participaram deste grupo e este número passou para 43 mulheres em 1981 (Bahamondes et al., 1984).

A partir de 1986, com a inauguração do Caism, foram criados ambulatórios e enfermarias específicas para atendimento à mulher com câncer ginecológico e de mama. Assim, as mulheres operadas por câncer de mama e internadas na enfermaria de oncologia eram sistematicamente atendidas pelo programa de reabilitação. Desde então, a rotina de atendimento vem se modificando progressivamente, com o objetivo principal de prevenir e minimizar complicações visando à melhorar a QV.

Hoje, a inclusão inicia-se no pré-operatório e mantém-se por aproximadamente um mês após a cirurgia. Atualmente, este programa de reabilitação é composto por uma equipe multidisciplinar que inclui fisioterapeutas, enfermeiros, psicólogos e assistentes sociais, e se integra de maneira permanente e dinâmica com os

médicos. As mulheres recebem apoio e informações básicas e inicia-se o trabalho corporal. O número de pacientes que integra o grupo é sempre maior do que dez. O grupo é aberto, tendo uma constituição especial que permite um fluxo constante de pacientes, umas que começam e outras que terminam. De acordo com o incremento de novas técnicas, disponibilidade de recursos materiais e humanos, as condutas propostas por esta equipe sofrem constantes modificações.

Além do benefício físico-funcional esperado com o programa de reabilitação, não se pode excluir as repercussões deste programa sobre a QV das mulheres que lidam com o diagnóstico e tratamento do câncer de mama. Embora, como anteriormente descrito, a QV possa ser definida de diversas formas, ela pode ser quantificada e analisada através de questionários. Cada questionário utiliza escalas diversificadas de avaliação, podendo ser genéricas ou específicas para determinados aspectos da saúde do paciente. Instrumentos genéricos são usados para qualquer condição de saúde e permitem comparações entre diversas situações, independente da doença de base ser câncer ou não. Já os específicos são mais sensíveis e direcionados para avaliar uma condição determinada da saúde do paciente, como o câncer de mama. Além disso, alguns dos questionários podem ser auto-administrados, enquanto outros exigem a presença de um profissional habilitado para sua aplicação.

O *Functional Assessment of Cancer Therapy-Breast* (FACT-B) surgiu da necessidade de mensurar e documentar a QV em mulheres com câncer de mama e foi utilizado por estudos relevantes nesta área (Flessing et al., 2006; Mansel et al., 2006). Este modelo foi desenvolvido a partir do *Functional Assessment of Cancer*

Therapy-General, (FACT-G), que avalia de maneira geral a QV de pacientes oncológicos. O FACT-G é de fácil administração, breve, validado e analisa as principais mudanças ocorridas com o paciente. Apresenta a possibilidade de se verificar o peso relativo de determinados aspectos da QV, sob a ótica da paciente com câncer, através de subescalas relacionadas ao seu bem-estar físico, emocional, social e funcional (Cella et al., 1993). Ao FACT-G foi adicionada uma nova subescala, a *Breast Cancer Subescale* (BCS), que incluiu questões específicas relacionadas à QV no câncer de mama, dando origem ao FACT-B (Brady et al., 1997).

O FACT é, desde a década de 90, o instrumento mundialmente mais utilizado para avaliação da QV de pacientes com câncer. Selecionar um instrumento apropriado para avaliar a QV nos diversos estudos de intervenção em paciente com câncer inclui a capacidade de avaliar as necessidades do paciente decorrentes deste estudo, através dos itens incluídos no questionário e a sua validação. Apesar de não existir um questionário único capaz de avaliar a QV em qualquer tipo de estudo clínico, o FACT proporciona medidas genéricas e dirigidas com múltiplos benefícios, incluindo facilidade de administração, aplicação globalizada e interpretação objetiva e bem definida. As questões envolvem mais de 50 tipos de sintomas, desde sintomas inicias até doença avançada, incluindo cuidados paliativos. Inclui múltiplas opções de escores com várias subescalas e aborda diversos efeitos do tratamento em cada tipo de câncer. É fácil de completar, demonstrando equivalência no modo de administrar, podendo o paciente ser entrevistado ou ele próprio responder às questões (Webster et al.,2003).

O FACT demonstrou boa reprodutibilidade e consistência interna, validade, sensibilidade e foi traduzido e pré-testado em mais de 45 línguas. Foi validado para populações especiais, como idosos e aqueles que vivem em zonas rurais, e pode ser apropriado para pacientes com doenças crônicas e população em geral. Aborda também considerações espirituais, cuidados paliativos e satisfação com tratamento. O FACT é o questionário atualmente mais utilizado nos estudos clínicos em pacientes com câncer, incluindo os estudos multicêntricos, interinstitucionais, internacionais, financiados por fundos privados ou governamentais. É também o questionário mais utilizado para analisar os resultados dos estudos das práticas de saúde (Webster et al.,2003).

Em 2004 a BLS foi introduzida no Caism/UNICAMP, como nova abordagem cirúrgica para as mulheres com tumores iniciais. A equipe de reabilitação se deparou com novas necessidades e questionamentos sobre os critérios para encaminhamento destas mulheres, principalmente se deveriam participar de todas as etapas do programa de reabilitação, considerando a menor morbidade físico-funcional. Inicialmente a equipe de reabilitação optou que todas as mulheres com câncer de mama submetidas à cirurgia, independentemente da abordagem axilar, continuassem como integrantes em todas as atividades do grupo. Entretanto, a necessidade da reabilitação físico-funcional das mulheres submetidas à BLS precisa ser avaliada e motivou a realização do presente estudo. É relevante avaliar os benefícios tanto físico-funcionais quanto nos diferentes aspectos na QV, almejados com o programa de reabilitação.

No Caism são atendidos, por ano, cerca de 400 casos novos de câncer de mama. Dentre eles, 30% são diagnosticados com o tumor inicial e, portanto, suas portadoras são candidatas a realizar a BLS. Aparentemente a BLS beneficia as mulheres operadas por diminuir a morbidade pós-operatória. Porém, não se sabe ainda se estas mulheres são beneficiadas com a reabilitação. A análise da recuperação físico-funcional e da QV destas mulheres pode direcionar melhor a intervenção fisioterapêutica e da equipe de reabilitação neste serviço, assim como influenciar estas práticas em outros locais.

2. Objetivos

2.1. Objetivo Geral

Avaliar a QV e a recuperação físico-funcional das mulheres com câncer de mama inicial submetidas à BLS ou à LA, com ou sem intervenção do programa de reabilitação.

2.2. Objetivos Específicos

- ***Artigo 1 – Implications of a postoperative rehabilitation program on quality of life in women with primary breast cancer treated with sentinel lymph node biopsy or complete axillary lymph node dissection***

  Avaliar o impacto do programa de reabilitação na QV de mulheres com câncer de mama inicial, 30 dias e seis meses após a cirurgia, comparando àquelas submetidas a BLS, com ou sem inserção no programa de reabilitação, e LA com reabilitação.

- ***Artigo 2 – Rehabilitation program including physical therapy in postoperative care of breast cancer patients: effects on shoulder range of motion, lymphedema and axillar web syndrome comparing sentinel lymph node and axillary lymph node dissection***

  Avaliar o impacto do programa de reabilitação na recuperação físico funcional de mulheres com câncer de mama inicial, 30 dias e seis meses após a cirurgia, comparando àquelas submetidas a BLS, com ou sem inserção no programa de reabilitação, e LA com reabilitação.

3. Publicações

Artigo 1 - ***Implications of a postoperative rehabilitation program on quality of life in women with primary breast cancer treated with sentinel lymph node biopsy or complete axillary lymph node dissection***

Artigo 2 - ***Rehabilitation program including physical therapy in postoperative care of breast cancer patients: effects on shoulder range of motion, lymphedema and axillar web syndrome comparing sentinel lymph node and axillary lymph node dissection***

3.1. Artigo 1

16-Jun-2008

Dear Ms. Pinto e Silva:

Your manuscript entitled "Implications of a postoperative rehabilitation program on quality of life in women with primary breast cancer treated with sentinel lymph node biopsy or complete axillary lymph node dissection" has been successfully submitted online and is presently being given consideration for publication in the Annals of Surgical Oncology.

Your manuscript ID is ASO-2008-06-0521.

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Sincerely,
Annals of Surgical Oncology Editorial Office

Implications of a postoperative rehabilitation program on quality of life in women with primary breast cancer treated with sentinel lymph node biopsy or complete axillary lymph node dissection

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ABSTRACT

Background: The aim of this clinical study was to evaluate quality of life (QoL) in early-stage breast cancer patients and to investigate the effects of a comprehensive rehabilitation program comparing women undergoing sentinel node biopsy (SNB) versus complete axillary lymph node dissection(ALND). QoL was assessed with the Functional Assessment of Cancer Therapy - General and Functional Assessment of Cancer Therapy – Breast (FACT-B®) questionnaire. **Methods:** Eighty-nine women with histologically confirmed primary breast cancer stages I-II were enrolled. Recruitment began on May 2006 and ended on December 2007. According to current standards of care, 58 women were found clinically fit to undergo SNB, and the other 31 were elected for ALND. Thirty women who underwent SNB were randomly allocated to participate in a comprehensive postoperative rehabilitation program, and the 28 remainder were dismissed and scheduled to return for clinical follow-up. **Results**: Women undergoing ALND had a better QoL within 30 days of surgery on the FACT-B, FACT-G; Trial Outcome Index (TOI), emotional well-being (EWB) and breast concern subscale (BCS) ($p<0.005$) and at 6 months after surgery on the EWB subscale only. Women undergoing SNB had a significant improvement in QoL only on the EWB subscale 6 months after surgery in the group with rehabilitation and 30 days after urgery in the group without rehabilitation. **Conclusion:** Women undergoing ALND benefitted from a rehabilitation program and had a better QoL. Women undergoing BLS, regardless of rehabilitation, showed improvement in QoL for the emotional well-being subscale only.

Keywords: sentinel lymph node, breast cancer, quality of life

Introduction

Axillary lymph node status is an important prognostic factor in women with breast cancer. Nonetheless, axillary lymph node dissection (ALND) may be associated with upper limb morbidity[1]. In recent years, sentinel node biopsy (SNB) has become the mainstay of standard care for axillary staging in women with initial breast cancer (clinical stages I and II). SNB avoids unnecessary trauma to the lymphatic drainage systems of the axilla, at the same providing reliable staging for the clinically negative axilla[2]. The use of SNB brought a reduction in arm morbidity, numbness, pain, arm swelling, motion restriction and lymphedema.[2,3,4,5]

The majority of clinical studies on breast cancer focuses on treatment and survival. However, with a greater longevity promoted by advances in therapeutics and early diagnosis, interest has shifted to the assessment of quality of life (QoL).

The confirmed advantages of SNB over ALND regarding arm proficiency may have an impact on QoL, however, this is still an ongoing debate. In the ALMANAC trial, a randomized study including 1031 women assigned to undergo SLN (515) or standard axillary surgery (516), assessed by the Functional Assessment of Cancer Therapy – Breast (FACT-B) questionnaire, demonstrated that QoL improved in patients receiving SNB compared with standard ALND.[3]

Based on clinical experience and common sense, most physicians usually agree that postoperative rehabilitation programs may be an important part in the treatment of women with early breast cancer. However, there has been no firm confirmation of the effects of these programs. In our service, we provide a rehabilitation program in which patients enjoy peer support group activities, share personal experiences and obtain individualized psychological support when necessary. On a psychological level, the aim of the program is to encourage

patients to express their feelings and conflicts, offering support by providing specific information and guidance. Patients concomitantly undergo a tight physical therapy regimen to improve recovery of arm movement. Furthermore, rehabilitation programs are a time-saving cost-effective method in the treatment of chronic disease.[6]

In this prospective clinical study, covering a 6-month period, we assessed QoL in women with early-stage primary breast cancer, treated with quadrantectomy and either SNB or complete ALND. All women undergoing ALND participated in rehabilitation while those undergoing SNB were randomized to be included or not in the rehabilitation group. With this approach, we carried out a comprehensive analysis of the impact of surgical modalities and interventional rehabilitation on QoL, thereby deepening the understanding of the management needed to decrease ailments in women with early breast cancer.

Patients and Methods

Patient selection and study design

A longitudinal clinical study was conducted using three groups of patients. Study participants were women treated for stages I and early II primary breast cancer at the Women's Integral Health Care Center *University of Campinas* – UNICAMP. We recruted women undergoing quadrantectomy or simple mastectomy for local surgical treatment, who had no evidence of distant metastases and no prior malignancy. These women signed an informed consent form previously approved by the hospital ethics revision board, established in the Helsinki Declaration (World Medical Association, 1996). Patient recruitment began in May 2006 and ended in December 2007.

On the day before surgery, all 89 women included in the study were examined and responded to an interview about clinical and social demographic characteristics. According to

a standardized service protocol, 58 women were found clinically fit to undergo SNB only. Fifty-six of these women underwent quadrantectomy and two underwent mastectomy (one because of multicentric disease and the other due to central tumor location and a very small breast). The remaining 31 women in the study underwent quadrantectomy with ALND. Eight of these women had been initially selected for SNB but the procedure was converted into ALND intraoperatively due to tumor invasion of the sentinel lymph node. Thirty women who underwent SNB were randomly allocated to a comprehensive postoperative rehabilitation program; from now on named "SNB with rehabilitation" and the remaining 28 patients were selected for clinical follow-up, from now on named "SNB without rehabilitation". All women who underwent ALND engaged in the rehabilitation program.

The SNB group without rehabilitation was scheduled for physical examination and asked to complete a questionnaire at 30 days after surgery. Of this group, only one woman missed this evaluation. All patients were scheduled for a late evaluation of physical examination and questionnaire at 6 months after surgery, when 80 patients were assessed. Of the nine women who missed this last evaluation, three were from the ALND group, four were from the BLS group with rehabilitation and two were from the BLS group without rehabilitation. On pathologic analysis of the breast specimen, three women had compromised margins after quadrantectomy. Two patients with positive or compromised margins proceeded to have further excision of the surgical margin and one had a complete mastectomy. Patients were treated with adjuvant irradiation and systemic endocrine or chemotherapy according to the standard institutional protocols.

Surgical techniques

Sentinel lymph nodes identification and breast tumor removal were performed according to a standardized protocol using blue dye. The patient received general

anesthesia in the operating room. Three to five minutes before the first incision was made, 2mL of Patent Blue V dye (Laboratoire Guerbet, Aulnay-sous-Bois, France) were injected into the peritumoral and periareolar region. Intraoperative identification of sentinel lymph nodes was based on blue dye mapping. All nodes that stained blue were defined as sentinel lymph nodes. After completion of sentinel lymph node biopsy, a quadrantectomy (56) or a simple mastectomy (2) was performed to remove the primary tumor. All specimens were sent for routine pathology evaluation.

ALND was initiated, identifying the lateral margin of the pectoralis major muscle, proceeding with dissection of the interpectoral space until the apical portion of the axillary vein. After performing level III lymphadenectomy, dissection continued in a craniocaudal direction, identifying the intercostobrachial (ICB) nerve at the second intercostal space where it emerges in the thoracic wall. In order to complete axillary lymphadenectomy, all lymph adipose tissue surrounding the nerve (level I) and its branches was dissected until the ICB nerve enters the lateral skin flap. ALND always included the three levels of axillary lymph nodes.[7]

Patient interview

On the day before surgery women were invited to participate in the trial. After agreeing to enroll, these women responded to the first interview, from now on named "preoperative moment". These potential subjects were then maintained under close surveillance by the investigators. Patients who participated in the postoperative rehabilitation program and all who eventually received adjuvant therapies (radio, endocrine and chemo) were given the whole treatment in the same hospital. The task of keeping track of patient outcome and contacting patients for interview was thus facilitated. During follow-up, patients were examined at 2 distinct time periods. These times differed according to

engagement in rehabilitation intervention: women who were undergoing rehabilitation attended the second physical examination in the end (last day) of the program, usually 30 days postoperatively. Women who were not randomized for postoperative rehabilitation were examined at a follow-up clinical visit that was scheduled 30 days postoperatively. All women were asked to return for a physical evaluation six months after surgery.

Postoperative rehabilitation program

The goal of the rehabilitation program was to improve the ability to cope with the disease and adverse effects of treatment, thereby improving QOL in these women. Rehabilitation was provided by a multidisciplinary team: physical therapists, social workers, nurses and psychologists. Intervention meetings were provided for each group (10 to 20 patients) three times a week during four weeks after surgery.

Physical therapy technique consisted of 19 types of exercise. Three exercises were performed on the first day after breast cancer surgery.[8,9] Advice on arm care and lymphedema management was given to the patients, in addition to a booklet illustrating the content of educational sessions with photos of the exercises. Forty-eight hours after surgery, the patients were scheduled to return to the Outpatient Physical Therapy Clinic to participate in a 40-minute exercise program that would be done three times per week.

Social orientation consisted of one-hour sessions, once a month. During these meetings, patients received social support with information and orientation concerning patient civil rights following breast cancer surgery. Counseling included information on social insurance, work permits, financial concerns, employment, free transportation and others. When required, individual consultations were scheduled.

Nursing care consisted of one-hour sessions once a month with a specialized nurse. These meetings focused on educating the patient about wound and operated limb care, in

addition to vacuum drain management when used. The women were given appropriate verbal information on surgery and hospital stay, as well as advice on community support. Furthermore, the husbands of these women were also informed about these issues. Individual consultations were arranged for patients with vacuum drains and/or seroma. Drain management was explained three times a week until complete recovery and drain removal, which usually occurred after two weeks.

Psychological assessment and advice meetings took place once a week during four weeks. The aim of such therapy was to listen (to) and help women overcome emotional difficulties, improve mood, enhance coping, better perceive vitality, decrease symptoms of depression and anxiety and thereby improve QOL.

Questionnaires for QoL Assessment

Functional Assessment of Cancer Therapy – Breast FACT-B questionnaire.

Quality of life was measured by the FACT-B, a scale specifically designed for use among breast cancer patients (Cronbach's alpha= 0.88).[10] This 44-item scale consists of five subscales: physical well-being (PWB; seven items), social well-being (SWB; seven items); emotional well-being (EWB, six items); functional well-being (FWB; seven items) and additional concerns specific to breast cancer patients, such as an altered sense of femininity, feelings of decreased attractiveness, and problems associated with treatment-related arm swelling included in the breast cancer subscale (BCS; nine items). The difference in overall health-related QoL was assessed by the FACT-B Trial Outcome Index (TOI). The TOI is the sum of the PWB, FWB and BCS of the FACT-B questionnaire (twenty-three items). Each item is answered on a 5-point likert scale from 0 to 4, with the summation of responses. In all FACT-B summary scores, including TOI, a high score indicate a good QoL. Negatively framed statements were reversed after scoring, according to manual

instructions for version 4 of the functional assessments system[10]. The FACT-B is appropriate for use in oncology clinical trials, as well as in clinical practice. It demonstrates ease of administration, brevity, reliability, validity, and sensitivity to change. The Portuguese version was used, after permission given by Ben Arnold from the FACIT organization. The test was administered and scored in accordance with manual instructions for the version 4 of the Functional Assessment of Chronic Illness Therapy (FACIT) measurement system[10].

A specifically designed questionnaire was used in the first interview to ascertain the sociodemographic and clinical characteristics of the patients

Statistical analysis

To evaluate homogeneity among the groups the chi-square tests, the ANOVA or Kruskal-Wallis (non-normal distribution) tests were used. A comparison between 30 days and 6 months was made for each group, obtaining the percentage variation regarding the initial time period and using the Paired Student's t test or Wilcoxon signed rank test (for non-normalized data). The same tests were used to evaluate chemotherapy effect among the scores, since the groups were not homogeneous. There was a significant difference in the BCS domain. To evaluate both group effect and time effect (pre, 30 days and 6 months), the ANOVA test for repetead measures was used (using the BOX-COX mathematic transformation for normalized data), and a covariable for chemotherapy control was included for the BCS domain. SAS software version 9.02 wa used for analysis.

Results

Patient age ranged from 31-84 years. The age distribution of the study groups (ALND, SNB with rehabilitation and SNB without rehabilitation) was statistically similar ($p=0.29$). Body Mass Index (BMI) ($p=0.12$) and laterality ($p=0.09$) did not differ across

the study groups. The majority of women had no axillary metastases on pathological assessment (79%). Among the women undergoing SNB, a mean of two axillary lymph nodes per woman were removed in both groups (p=0.59). As expected, however, a greater proportion of women received adjuvant chemotherapy in the ALND group (81%) than in the SNB groups (53% with rehabilitation and 39% without rehabilitation) (p<0.01). It was observed that QoL at baseline was similar and very good in the three groups with mean FACT-B ranging from 103.7 (SD=24.3) in women undergoing ALND, to 107.0 (17.5) in women undergoing SNB with rehabilitation to 107.5 (SD=15.9) in women undergoing SNB without rehabilitation. These high mean FACT-B values were maintained in all subscales (Table 1).

Tables 2, 3 and 4 show the course of QoL at 30 days and six months for each group, considering women undergoing ALND and those undergoing SNB with and without postoperative rehabilitation. Women undergoing ALND had a better QoL within 30 days of surgery on the FACT-B (p=0.0117); FACT-G (p=0.0425); TOI (p=0.0104); EWB (p=0.0003) and BCS (p=0.001). This improvement remained significant 6 months after surgery on the EWB subscale (p=0.0204) (Table 2). On the other hand, women undergoing BLS had a better QoL only on the EWB subscale, which was significant 6 months after surgery in the group with rehabilitation (p=0.0334) (Table 3) and 30 days after surgery in the group without rehabilitation (p=0.0386) (Table 4). Chemotherapy did not interfere with QoL in the three groups.

Comparing the mean FACT-B and its diverse subscales among the different groups at the three time periods evaluated, we observed no difference in QoL among the groups at any time period studied. In a similar manner, the EWB subscale improved significantly (p=0.0041) for all groups with time (Table 5).

Discussion

In the preoperative period, a good QoL was found in the three groups in a similar manner for all the FACT-B subscales. There was no difference among the groups at any time period studied. Women undergoing ALND had a significant improvement in QoL 30 days after surgery, at the end of the rehabilitation program, on general assessment in all the physical subscales and in the emotional subscale. This improvement remained significant on the emotional well-being subscale at 6 months after surgery. Women undergoing BLS, regardless of rehabilitation, showed improvement on the emotional well-being subscale only.

The present study enhances the understanding of the combined effects of physical ailments imposed by different modalities of axillary dissection and rehabilitation on QoL of women with low-stage breast cancer. In the short term, current data suggests that the type of axillary dissection affects QoL. The FACT scores varied as a result of the axillary surgical approach. The end of the rehabilitation program occurred within 30 days of surgery, when QoL scores were highest throughout the study period, among women who had participated in the program and had undergone ALND. From these results, it may be reasonable to infer that expressions of support for the psychological and physical demands of the patients have a great impact on overall QoL in the ADLN group.

The concept that there is a clear impact of SNB on QoL was corroborated by the present study. Since the SNB procedure requires less trauma to the axillary space, it should cause less arm/shoulder morbidity such as motion restriction, hypoesthesia, paraesthesia, lymphedema, loss of muscular strength than ALND.[11,12,13] The overall QoL of women undergoing SNB, especially in physical terms, should be higher when compared to their counterparts facing ALND. However, some researchers have observed a reduction in muscular strength and hypoesthesia on the operated side in women undergoing SNB.[14,15]

These early reports have been criticized by many authors on the grounds that surgeons involved in those studies may have been at an early stage in their learning curves for SNB. As a result, axillary dissection for sentinel lymph node identification may have been increased. Such criticism was later dismissed,when in-depth research was done to compare morbidity inflicted by surgeons at an early stage in their learning curves with that inflicted by more experienced surgeons.[16]

Even in the hands of experienced surgeons, SNB may be physically hazardous to women.[17] On the other hand, it has been confirmed that lymphedema and restriction of arm/shoulder mobility is consistently more present after ALND than after SNB but this type of physical morbidity may not have a significant expression in terms of QoL.[1,4,5] Dubernard et al[18] concluded that axillary procedures affect only QoL related to arm morbidity. We agree with a statement formulated by Rietman et al[1] that says: "although an association between upper limb morbidity and poor QoL was described, QoL is seldom considered in the debate on axillary approach."

Appropriate education and guidance aids in speeding up recovery after breast surgery. Even women treated with SNB may wish to gain information on the difficulties that may arise, and certainly want to be educated about the entire treatment course and disease management. In the present series, the group randomized to not participate in rehabilitation had no negative impact to be excluded. The service caring for these patients also provides information at the time of diagnosis, regardless of rehabilitation. Nursing and social service workers who manage these patients at the time of diagnosis also participate in the immediate postoperative rehabilitation program. As a result, these professionals acquire certain communication skills and are able to educate these women even before surgery. It is known that patients who have sufficient knowledge of the

disease apparently fare better and overcome conflicts more readily. For example, nurses are now recognized as key members of breast cancer recuperation, providing a continuum of services related to body care that begin at the preoperative period.[19]

Postoperative rehabilitation programs offer information and guidance regarding exercise, arm mobilization, hygiene, surgical wound and scar formation, social rights, emotional aspects that have a major impact on QoL in women undergoing ALND.[8,20] These aspects should facilitate a better reintegration into normal livibg, considering the general concept of QoL, as adopted by WHO[21] " a person's perception of his/her position in life within the context of the culture and value systems in which he/she lives and in relation to his/her goals, expectations, standards, and concerns. It is a broad-ranging concept incorporating, in a complex way, the person's physical health, psychological state, level of independence, social relationships, personal beliefs, and relationship to salient features of the environment".

Although the role of physical activity in QoL of women undergoing SNB is yet to be fully known, physical therapy through exercises should benefit the physical well-being, functioning, feelings and QoL in these patients. Doing rehabilitation exercises following ALND is essential to minimize postoperative complications such as shoulder dysfunctions, lymphedema and pain.[8] ALND is known to reduce range of motion (ROM) of the affected shoulder joint, lymphedema, numbness, muscle strength, and arm disorders, making physical therapy necessary to facilitate daily activities and improve QoL.[6,15,20]

Other components of the postoperative rehabilitation program, such as social advice and psychotherapy, may also improve QoL in women with ALND. During breast cancer therapy, there are increasing emotional and existential concerns. The patient needs to cope with her feelings and emotional distress in an attempt to maintain a sense of normality, avoiding changes in routine patterns of life.[22,23] An important feature of the present study was

the form of QoL assessment. The concept of QoL is wide and encompasses several domains, ranging from physical to psychological. None of the many existing tools used to assess QoL is comprehensive enough to address all aspects and information is never complete.

It is a well-known fact that physical and psychological symptoms may vary and persist in the first several years after therapy.[1] The limited duration of the present study precludes the evaluation of long-term differences in QoL related to SNB and ALND. Moreover, it is also important to ascertain whether the advantages derived from rehabilitation persist over longer periods of time. We are aware that a long-term follow-up is needed to fully understand the long-term and late effects of postoperative rehabilitation programs in these women.

In conclusion, multidisciplinary care is now considered fundamental to improve the most diverse outcomes in women with breast cancer, regardless of the aggressiveness of the surgical treatment chosen. This study supports the theory that breast cancer patients undergoing ALND, must be included in a postoperative rehabilitation program after surgery, due to the real benefits to QOL that may arise in the short term. Regarding SNB, all women presented a significant improvement in the emotional well being, unrelated to the rehabilitation program attendance.

Table 1. Baseline Characteristics of the 89 patients

	n	ALND (n=31)	SNB With rehabilitation (n=30)	SNB without rehabilitation (n=28)	P
Age (years)					
Range	31 to 84	37 to 84	31 to 79	37 to 80	
95% central range	37 to 79.9	38.5 to 81.0	32.2 to 72.7	37.8 to 79.3	
Mean	55.5	56.5	52.3	57.2	
Median	55.0	55.0	49.5	56.5	0.29
BMI (sd)	27.5 (5.8)	28.1 (4.5)	28.4 (6.1)	25.9 (6.9)	0.12
Laterality					
Right (%)	41 (46)	16 (52)	9 (39)	16 (59)	
Left (%)	48 (54)	15 (48)	21 (61)	12 (41)	0.09
Axillary metastasis found					
Zero (%)	71 (79)	15 (45)	30 (100)	28 (100)	
1 to 3 (%)	13 (15)	13 (39)	0 (0)	0 (0)	
>=4 (%)	5 (6)	5 (16)	0 (0)	0 (0)	
Mean number of LN dissected (sd)		-	1.8 (0.9)	2.0 (1.0)	0.58
Adjuvant Chemotherapy	52 (58)	25 (81)	16 (53)	11 (39)	**<0.01**
FACTB (O-144)		103.7 (24.3)	107.0 (17.5)	107.5 (15.9)	0.6744*
FACTG (O-108)		80.5 (18.6)	81.5(14.4)	82.3 (14.1)	0.9482**
TOI (O-92)		64.7 (16.5)	68.9(10.6)	67.7 (9,8)	0.6796**
EWB (O-24)		18.1 (4.7)	18.4(4.1)	18.2 (4,1)	0.9623**
PWB (O-28)		22.6 (5.7)	24.0(3.1)	22,8 (4.5)	0.7607**
FWB (O-28)		18.9 (6.0)	19.4(5.3)	19,7 (5.2)	0.8742**
SWB (O-28)		20.9 (6.0)	19.8(6.1)	21,6 (4.1)	0.5159**
BCS (O-36)		23.2 (6.8)	25.5(4.7)	25,2 (4.5)	0.5858**

SD = standard deviation; BMI= Body Mass Index *Anova **Kruskal ***Chi square; EWB = emotional well-being; PWB = physical well-being; FWB = functional well-being; SWB = social well-being

Table 2. Variation of mean FACT-B scores after interval corresponding to the end of postoperative rehabilitation programs

	ALND					
	Percentage variation					
	30 days X preoperative			6 months X preoperative		
	Mean%	Std	P-value	Mean%	Std	Valor-p
FACTB	8.5	(17.6)	**0.0117**	2.1	(18.2)	0.9118*
FACTG	6.3	(18.4)	**0.0425***	0.5	(18.2)	0.4094*
TOI	9.1	(19.3)	**0.0104***	1.5	(24.9)	0.8419*
EWB	30.8	(85.2)	**0.0003***	23.7	(94.4)	**0.0204***
PWB	7.6	(28,6)	0.2971*	-3.7	(30.3)	0,5233
FWB	6.2	(37.6)	0.7359*	5.1	(42.0)	0.6714*
SWB	8.5	(55.3)	0.9584*	5.4	(44.1)	0.6662*
BCS	18.9	(28.9)	**0.0010**	9.5	(28.3)	0.0858

EWB = emotional well-being; PWB = physical well-being; FWB = functional well-being; SWB = social well-being; BCS = breast cancer subscale. Paired Student's t test, * Mann-Whitney test

Table 3. Variation of mean FACT-B scores after six months

	BLS with rehabilitation Percentage variation					
	30 days X preoperative			6 months X preoperative		
	Mean%	Std	Valor-p	Mean%	Std	P-value
FACTB	0.6	(19.9)	0.4693*	-2.0	(18.0)	0.5127
FACTG	-0.1	(21.2)	0.9765*	-4.4	(19.2)	0.2341
TOI	-1.5	(20.5)	0.9180*	-2.8	(18.2)	0.3526
EWB	12.7	(43.0)	0.0582*	15.0	(35.6)	**0.0334***
PWB	0.3	(25.6)	0.8753*	-7,5	(16.0)	0.0632*
FWB	-5.4	(32.4)	0.4119	-5.5	(36.9)	0.2576
SWB	2.7	(29.3)	0.6455	-7.1	(37.2)	0.3848
BCS	4.3	(30.2)	0.4808	8.2	(30.3)	0.5085*

EWB = emotional well -being; PWB = physical well- being; FWB = functional well-being; SWB = social well -being; BCS = breast cancer subscale. Paired Student's t test, * Mann-Whitney test

Table 4. Variation of mean FACT-B scores after six months

	BLS withtout rehabilitation Percentage variation					
	30 days X preoperative			6 months X preoperative		
	Mean%	Std	P-value	Mean%	Std	P-value
FACTB	5.7	(17.2)	0.0796	-3.5	(16.2)	0.2782
FACTG	7.1	(25.5)	0.1997*	-5.1	(17.5)	0.1522
TOI	4.6	(15.3)	0.0967*	-3.3	(18.2)	0.3661
EWB	13.6	(34.0)	**0.0386***	4.9	(21.8)	0.2664
PWB	9.8	(37.2)	0.1800*	-6.3	(22.6)	0.1709
FWB	7.6	(41,4)	0.7955*	-3.5	(35.9)	0.1897*
SWB	6.6	(28.7)	0.2280*	-9.0	(23.1)	0.0581
BCS	5.9	(19.5)	0.1093	3.5	(23.4)	0.4597

EWB = emotional well-being; PWB = physical well- being; FWB = functional well-being; SWB = social well-being; BCS = breast cancer subscale. Paired Student's t test, * Mann-Whitney test

Table 5. Mean baseline score differences between groups over time

	Pre-operative			30 days			6 months	
	ALND	SNB + R	SNB - R	ALND	SNB + R	SNB - R	ALND	SNB + R
FACT	Mean (sd)	Mean (sd)	Mean (sd)	Mean(sd)	Mean (sd)	Mean (sd)	Mean(sd)	Mean (sd)
FACT -B	103.7 (24.3)	108.3 (16.7)	108.6 (16.8)	108.6 (20.9)	105.9 (21.0)	112.7 (16.5)	104.1 (22.6)	104.9 (21.5)
FACT -G	80.5 (18.6)	82.7 (14.0)	83.1 (15.0)	82.4 (16.4)	79.6 (17.3)	86.1 (13.1)	79.4 (16.4)	78.0 (18.0)
TOI	64.7 (16.5)	70.1 (9.4)	68.0 (10.5)	67.9 (13.9)	66.7 (12.8)	70.3 (10.8)	64.1 (15.7)	67.2 (13.7)
EWB	18.1 (4.7)	18.4 (4.1)	18.5 (4.2)	20.3 (3.6)	19.5 (4.5)	20.0 (4.0)	19.7 (4.1)	20.3 (3.3)
PWB	22.6 (5.7)	24.7 (2.4)	22.5 (4.7)	23.1 (4.2)	23.3 (4.5)	23.7 (4.1)	21.1 (5.5)	22.9 (4.8)
FWB	18.9 (6.0)	19.8 (5.0)	20.0 (5.5)	18.6 (6,0)	17.1 (5.3)	20.0 (4.6)	18.3 (4.9)	17.5 (6.7)
SWB	20.9 (6.0)	19.8 (6.3)	22.1 (4.0)	20.4 (5.4)	19.7 (6.3)	22.5 (4.2)	20.3 (5.5)	17.4 (7.3)
BCS	23.2 (6.8)	25.6 (4.7)	25.6 (4.7)	26.3 (5.5)	26.4 (5.3)	26.6 (5.5)	24.7 (7.0)	26.9 (5.4)

* Assess the difference between mean scores obtained from women undergoing ALND, those undergoin and without rehabilitation. EWB = emotional well- being; PWB = physical well- being; FWB = functional social well- being

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3.2. Artigo 2

6/6/2008 08:01

Re: Submission The Breast

Dear Physiotherapy Pinto e Silva,

Your submission entitled "Rehabilitation program including physical therapy in the postoperative care of breast cancer patients: effects on shoulder range of motion, lymphedema and axillary web syndrome comparing sentinel node biopsy and axillary lymph node dissection" has been assigned the following manuscript reference number: THEBREAST-D-08-174. Your manuscript is now with the editor.

Please quote the reference number in all future communications.

Yours sincerely,

Editorial Office
The Breast

Rehabilitation program including physical therapy in the postoperative care of breast cancer patients: effects on shoulder range of motion, lymphedema and axillary web syndrome comparing sentinel node biopsy and axillary lymph node dissection

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Summary

The aim of this clinical study was to evaluate shoulder range of motion, lymphedema and axillary web syndrome for early-stage breast cancer patients before and six months after surgery and to investigate the effects of a comprehensive rehabilitation program comparing women undergoing sentinel node biopsy versus complete axillary lymph node dissection. In the ALND group, there was a decrease in flexion and in abduction deficits throughout follow up. We found no movement deficits in women undergoing SNB procedure. There were two cases of AWS and no increase in circumference measurements of ipsilateral limbs. A rehabilitation program including physical therapy is essential in the post operative care of women who underwent ALND. We support the theory that SNB is associated with a very low rate of arm morbidity in a short-term follow-up and our results did not allow us to exclude SNB patients from all aspects of a rehabilitation program.

Keywords: Physical therapy; Breast cancer; Rehabilitation; Sentinel node biopsy; Axillary lymph node dissection; Morbidity.

Introduction

Axillary lymph node dissection (ALND) is performed essentially for staging purposes in women with clinical stage I and early-stage II breast cancer[1]. There have been some questions about the procedure due to the relatively high postoperative shoulder and arm morbidity. In order to minimize morbidity, sentinel node biopsy (SNB) has been extensively studied and the procedure seems to be adequate for staging the axilla[2]. Since SNB requires less traumatic preparation of the axillary space, it should cause less dysfunction of shoulder range of motion (ROM), lymphedema and axillary web syndrome (AWS) than ALND[2,3,4]. However, some studies reported that women undergoing SNB had a reduction in muscular strength and hypoesthesia on the operated side[5,6]. An early learning curve for surgeons involved in the procedures was highlighted in previous studies. It may have led to increased axillary dissection for sentinel lymph node identification. There was no doubt that restriction of arm/shoulder mobility and lymphedema was consistently more present after ALND than after SNB[2,4,7]. Nevertheless, despite the skill of the surgeon and the low morbidity rate associated with SNB, the procedure is not without its complications[8]. Multidisciplinary care has been found to improve outcome in the postoperative period. There is strong evidence that physical exercise needs to be included as supportive therapy in the postoperative care of women undergoing ALND[9,10]. The performance of physical therapy has been widely discussed, taking into consideration shoulder movement, the optimal time and type of exercise to be done. In the majority of circumstances, women will gradually resume their normal preoperative activities two weeks after surgery to minimize shoulder movement limitation[9,11,12,13]. When physical therapy is begun in the first few days after surgery, several advantages can be achieved, such as the prevention of lymphedema, retraction and shoulder dysfunction. The patient is also encouraged to resume her normal daily activities by engaging in physical therapy[9,11,12,13]. The

main purpose of all physical rehabilitation programs is to prevent complications, providing a functional and adequate recovery. Consequently, quality of life (QoL) is improved in women treated for breast cancer. Nevertheless, controversy still exists as to the need for rehabilitation programs for women undergoing SNB.

The aim of this clinical study was to evaluate ROM, lymphedema and AWS in early-stage breast cancer patients before and six months after surgery, and to investigate the effects of a comprehensive rehabilitation program on women undergoing SNB and ALND.

Patients and Methods

Patient selection and study design

A longitudinal clinical study was conducted using three groups of patients. Study participants were women treated for stages I and early II primary breast cancer at the Women's Integral Health Care Center *University of Campinas* – UNICAMP. We recruited women undergoing quadrantectomy or simple mastectomy for local surgical treatment, who had no evidence of distant metastases and no prior malignancy. These women signed an informed consent form previously approved by the hospital ethics revision board, established in the Helsinki Declaration (World Medical Association, 1996). Patient recruitment began in May 2006 and ended in December 2007.

On the day before surgery, all 89 women included in the study were examined and responded to an interview about clinical and social demographic characteristics. According to a standardized service protocol, 58 women were found clinically fit to undergo SNB only. Fifty-six of these women underwent quadrantectomy and two underwent mastectomy (one because of multicentric disease and the other due to central tumor location and a very small breast). The remaining 31 women in the study underwent quadrantectomy with ALND. Eight of

these women had been initially selected for SNB but the procedure was converted into ALND intraoperatively due to tumor invasion of the sentinel lymph node. Thirty women who underwent SNB were randomly allocated to a comprehensive postoperative rehabilitation program, from now on named "SNB with rehabilitation" and the remaining 28 patients were selected for clinical follow-up, from now on named "SNB without rehabilitation". All women who underwent ALND engaged in the rehabilitation program.

The SNB group without rehabilitation was scheduled for physical examination and asked to complete a questionnaire at 30 days after surgery. Of this group, only one woman missed this evaluation. All patients were scheduled for a late evaluation of physical examination and questionnaire at 6 months after surgery, when 80 patients were assessed. Of the nine women who missed this last evaluation, three were from the ALND group, four were from the BLS group with rehabilitation and two were from the BLS group without rehabilitation. On pathologic analysis of the breast specimen, three women had compromised margins after quadrantectomy. Two patients with positive or compromised margins proceeded to have further excision of the surgical margin and one had a complete mastectomy. Patients were treated with adjuvant irradiation and systemic endocrine or chemotherapy according to the standard institutional protocols.

Surgical techniques

Sentinel lymph nodes identification and breast tumor removal were performed according to a standardized protocol using blue dye. The patient received general anesthesia in the operating room. Three to five minutes before the first incision was made, 2mL of Patent Blue V dye (Laboratoire Guerbet, Aulnay-sous-Bois, France) were injected into the peritumoral and periareolar region. Intraoperative identification of sentinel lymph nodes was

based on blue dye mapping. All nodes that stained blue were defined as sentinel lymph nodes. After completion of sentinel lymph node biopsy, a quadrantectomy (56) or a simple mastectomy (2) was performed to remove the primary tumor. All specimens were sent for routine pathology evaluation.

ALND was initiated, identifying the lateral margin of the pectoralis major muscle, proceeding with dissection of the interpectoral space until the apical portion of the axillary vein. After performing level III lymphadenectomy, dissection continued in a craniocaudal direction, identifying the intercostobrachial (ICB) nerve at the second intercostal space where it emerges in the thoracic wall. In order to complete axillary lymphadenectomy, all lymph adipose tissue surrounding the nerve (level I) and its branches was dissected until the ICB nerve enters the lateral skin flap. ALND always included the three levels of axillary lymph nodes[14].

Patient interview

On the day before surgery women were invited to participate in the trial. After agreeing to enroll, these women responded to the first interview, from now on named "preoperative moment". These potential subjects were then maintained under close surveillance by the investigators. Patients who participated in the postoperative rehabilitation program and all who eventually received adjuvant therapies (radio, endocrine and chemo) were given the whole treatment in the same hospital. The task of keeping track of patient outcome and contacting patients for interview was thus facilitated. During follow-up, patients were examined at 2 distinct time periods. These times differed according to engagement in rehabilitation intervention: women who were undergoing rehabilitation attended the second physical examination in the end (last day) of the program, usually 30 days postoperatively. Women who were not randomized for postoperative rehabilitation were examined at a

follow-up clinical visit that was scheduled 30 days postoperatively. All women were asked to return for a physical evaluation six months after surgery.

Postoperative rehabilitation program

The goal of the rehabilitation program was to improve the ability to cope with the disease and adverse effects of treatment, thereby improving QOL in these women. Rehabilitation was provided by a multidisciplinary team: physical therapists, social workers, nurses and psychologists. Intervention meetings were provided for each group (10 to 20 patients) three times a week during four weeks after surgery.

Physical therapy technique consisted of 19 types of exercise. Three exercises were performed on the first day after breast cancer surgery[9,15]. Advice on arm care and lymphedema management was given to the patients, in addition to a booklet illustrating the content of educational sessions with photos of the exercises. Forty-eight hours after surgery, the patients were scheduled to return to the Outpatient Physical Therapy Clinic to participate in a 40-minute exercise program that would be done three times per week.

Social orientation consisted of one-hour sessions, once a month. During these meetings, patients received social support with information and orientation concerning patient civil rights following breast cancer surgery. Counseling included information on social insurance, work permits, financial concerns, employment, free transportation and others. When required, individual consultations were scheduled.

Nursing care consisted of one-hour sessions once a month with a specialized nurse. These meetings focused on educating the patient about wound and operated limb care, in addition to vacuum drain management when used. The women were given appropriate verbal information on surgery and hospital stay, as well as advice on community support. Furthermore, the husbands of these women were also informed about these issues. Individual

consultations were arranged for patients with vacuum drains and/or seroma. Drain management was explained three times a week until complete recovery and drain removal, which usually occurred after two weeks.

Psychological assessment and advice meetings took place once a week during four weeks. The aim of such therapy was to listen (to) and help women overcome emotional difficulties, improve mood, enhance coping, better perceive vitality, decrease depressive and anxious symptoms and thereby improve QOL.

Measurements

Flexion and abduction of the arm were evaluated by goniometry. For these measurements, a universal full-circle manual goniometer was used. No passive support was given to the arm. The starting position for these movements was with the forearm horizontal and the palm facing the floor. Flexion measurements were taken with the patient in the supine position. Abduction was measured with the patient lying in the lateral position. Clinical endpoints of each shoulder movement were defined by compensatory movements of the shoulder and/or the trunk. ROM limitation was pain or an uncomfortable level of soft tissue tightness, beyond which the woman could not move her arm[9].

Lymphedema assessment was performed by measuring arm circumference at four designated points: 7.5 cm above the humeroradial joint, 7.5 cm below the humeroradial joint, at the ulnar styloid process in the wrist and at the metacarpophalangeal joints[9].

Diagnostic criteria for AWS were the presence of palpable and visible cords of tissue in the axilla during maximum shoulder abduction, with or without associated pain or limited shoulder ROM[3,16].

Statistical analysis

Statistical calculations were performed using the R environment for statistical computing[17]. Confidence interval was set at 95% and the threshold for statistical significance was established at p=0.05. The Shapiro-Wilk test was applied to determine whether continuous variables complied with normal distribution. This information was used to select statistical parametric and non-parametric methods in further analyses. Analysis of variance and the Kruskal-Wallis rank sum test, dependent on normality of the response variable, were used to assess differences in age, body mass index, number of axillary metastases and mean number of lymph nodes dissected across the study groups. Chi-squares were calculated to compare laterality and use of adjuvant treatments in the study groups. The Tukey's Honestly Statistical Difference test was used to determine pair-wise (between the study groups) differences in mean flexion and abduction at baseline and postoperative assessment. Paired t-tests were used to compare flexion and abduction obtained at baseline with flexion and abduction obtained at 30 days, and to compare these movements at 30-days with those at 6 months in the entire sample and within each of the study groups. The Fisher exact test was used to compare the proportion of women with lymphedema across the study groups. Scatter plots were produced and a regression line was derived to display variations in flexion and abduction of the affected arm in the study groups over time.

Results

Patient age ranged from 31-84 years. The age distribution of the study groups (ALND, SNB with rehabilitation and SNB without rehabilitation) was statistically similar (p=0.29). Body Mass Index (BMI) (p=0.12) and laterality (p=0.09) did not differ across the study groups. The majority of women had no axillary metastases on pathological assessment (79%). Among the women undergoing SNB, a mean of two axillary lymph nodes per woman

were removed in both groups (p=0.59). Radiotherapy was used to treat 63% of all women, and a similar proportion was found in each of the study groups (p=0.70). As expected, however, a greater proportion of women received adjuvant chemotherapy in the ALND group (81%) than in the SNB groups (53% with rehabilitation and 39% without rehabilitation) (p<0.01) (Table 2). The groups participating in the rehabilitation program were homogeneous regarding the number of sessions. There were no significant differences in preoperative mean flexion or abduction ROM among the groups.

Regarding shoulder ROM, in the ALND group there were significant decreases in flexion deficits measuring from –12.4° (p=0.001) to 4.2° (p=0.06) and in abduction deficits measuring from –24.1° (p<0.001) to 11.6° (p=0.01) at 30 days and 6 months postoperatively, respectively. Six months after surgery, there was a final significant flexion deficit measuring -7.3° (p=0.02) and abduction deficit measuring -11.5° (p=0.003), in comparison to the preoperative period in women from the ALND group only. We found no movement deficit in the SNB groups throughout the study (Table 3).

There were only two cases of AWS. Only a slight increase in circumference measurements taken at different sites in the upper limb ipsilateral to surgery was detected among the three groups, without any clinical significance during the follow-up period (Table 4).

Discussion

There was no statistical significance regarding shoulder ROM (flexion and abduction) among the groups. No movement deficits were found in women undergoing the SNB procedure. As previously described in the medical literature, women undergoing ALND will maintain some flexion and abduction deficit mainly for 30 days until they participate in a rehabilitation program. A steady but incomplete improvement occurs at six months following

surgery. In the SNB group, although physical therapy does not improve ROM or minimize the very rare complications of this surgical approach, rehabilitation programs still offer information and orientation on exercise, arm mobility, hygiene, surgical wound care and scar formation, social rights and emotional aspects that have an important impact on QoL, as previously depicted by other authors[18,19,20].

Exercise is essential in rehabilitation programs following ALND to minimize postoperative complications and consequently reduce ROM deficits in the affected shoulder joint, lymphedema, numbness, muscular strength and upper limb disorders, improving activities of daily living and positively affecting QoL in women[5,9,13]. Evidence shows that early physical therapy beginning on the week of surgery is beneficial to upper limb function because it reduces muscle wasting, stiffening and pain, as well as increased lymphatic drainage[9,15]. All these problems are known to aggravate upper limb limitations and many are difficult to reverse in patients who underwent ALND.

In this study, ROM deficits begin to resolve early, without any significant deficit 30 days following surgery, confirming the effectiveness of early intervention compared to delayed programs. Physical activity is effective, well tolerated and highly rewarding. Complementary behavioral intervention that enhances quality of life in women with breast cancer is currently well-known. Physical activity is associated with increased functional capacity, improved mood and body image and decreased emotional distress[10]. The program was fully acceptable to participants who developed more confidence to push themselves to exercise because of the security of having highly trained instructors. It was of particular interest that engaging in the exercise program neither precipitated nor exacerbated pre-existing lymphedema. The major benefit of the intervention group was the enormous

support women gained from each other. Many participants continued meeting socially after completing the program[21].

In a comparison of mid-term morbidity between SNB and ALND in breast cancer patients who received breast-conserving treatment, previous reports have suggested that SNB is associated with a very low rate of arm morbidity. However, rehabilitation programs were disregarded[2]. Swenson et al (2003)[22] compared women undergoing SNB with those undergoing ALND. As expected, the authors showed that ALND caused more arm impairment than SNB, producing a significantly higher deficit in shoulder flexion and abduction. This deficit interferes with the performance of daily activities. Although only short-term ROM deficits were consistently analyzed in most studies, AWS and lymphedema may be associated with ROM deficits in women undergoing ALND. AWS and lymphedema are two more common long-term complications in these patients.

Since appropriate education is important for quick patient recovery, even patients undergoing SNB should be informed and educated on the entire course of treatment and management of disease[23]. In this series, the focus was on short-term outcome and recovery was assessed within a six-month period. It is known that physical limitation may vary and persist in the first several years after therapy[1]. We are aware that a long-term follow-up is needed to fully understand the effects of rehabilitation programs on these women, as well as the late complications due to treatment.

AWS causes significant morbidity in the early postoperative period. In this study, AWS was a very rare complication encountered in both the SNB and ALND groups. Leidenius et al (2003)[3] showed that patients with AWS were thinner than those without AWS. On physical examination, tissue cords were less clearly visible and palpable under a thick subcutaneous layer. The problem may have been underestimated at least in the more obese

patients. A thicker layer of subcutaneous fat may also prevent skin adhesion to underlying tissues during the early phase of scar formation. This assumption is supported by findings that patients with limited ROM were usually thinner than those with normal ROM[3]. In this study, the BMI of all patients was greater than 25 (overweight) (Table 2).

Rönkä et al. (2005)[24] previously reported that lymphedema was almost insignificant after SNB. These authors depicted a small increase in arm circumference after ALND and SNB in the one-year follow-up visit. However, part of the ALND group (37%) received lymphatic drainage in the postoperative period. Leidenius et al (2005)[7] showed that 6% of women following ALND and 0% following SNB presented a greater than 2cm increase in wrist measurement ($p=0.0172$) in a 3-year follow-up period. We found no lymphedema among the groups in this study, which was designed to have a short-term follow-up period. Lymphedema evaluation requires a long-term follow-up because it is a late complication of ALND that is frequently associated with adjuvant radiotherapy[1,24]. Furthermore, it is not very easy to compare lymphedema rates since lymphedema assessment is done by measuring arm circumference and volume, data that is not totally accurate[7]).

In conclusion, this study supports the theory that early-stage breast cancer patients who underwent SNB should not be included in the entirety of rehabilitation programs after surgery. It is evident that multidisciplinary care is currently considered fundamental to improve diverse outcomes in women with breast cancer. After SNB, patients need to be included in all aspects of a rehabilitation program, e.g. psychological assessment, social counseling and nursing. Regarding physical therapy, a few individualized series of exercises should be proposed for two weeks after surgery instead of a complete program.

Table 1. Set of exercises

1. Neck muscle stretch.
2. Elevation, external and internal rotation of the shoulders.
3. Elbow flexion and extension in neutral position; to 90 degrees and maximum shoulder ROM.
4. Shoulder flexion and extension to maximum ROM accompanying metabolic exercises.
5. Active-assisted exercise of shoulder flexion touching the head.
6. Rotation of the wrist in shoulder flexion and abduction.
7. Elbow flexion and shoulder extension in abduction.
8. Shoulder abduction and adduction with hands in the occipital region.
9. Shoulder abduction with the elbows bent.
10. Shoulder extension using a cane.
11. Elbow flexion starting in exercise 10 position.
12. Diagonal sliding with one hand above the shoulder in the other at waist level.
13. Elbow flexion and extension in abduction of the shoulders. External and internal rotation of the shoulder in abduction of the shoulder.
14. Shoulder abduction – free active exercise.
15. Active shoulder flexion – assisted exercise maintained for 1 minute.
16. Shoulder abduction and adduction with the elbows bent.
17. Shoulder abduction – stretching maintained for 10 seconds.
18. Lateral shoulder abduction – stretching maintained for 10 seconds.
19. Functional diagonal of the shoulder – combination of shoulder flexion and abduction - stretching maintained for 10 seconds.

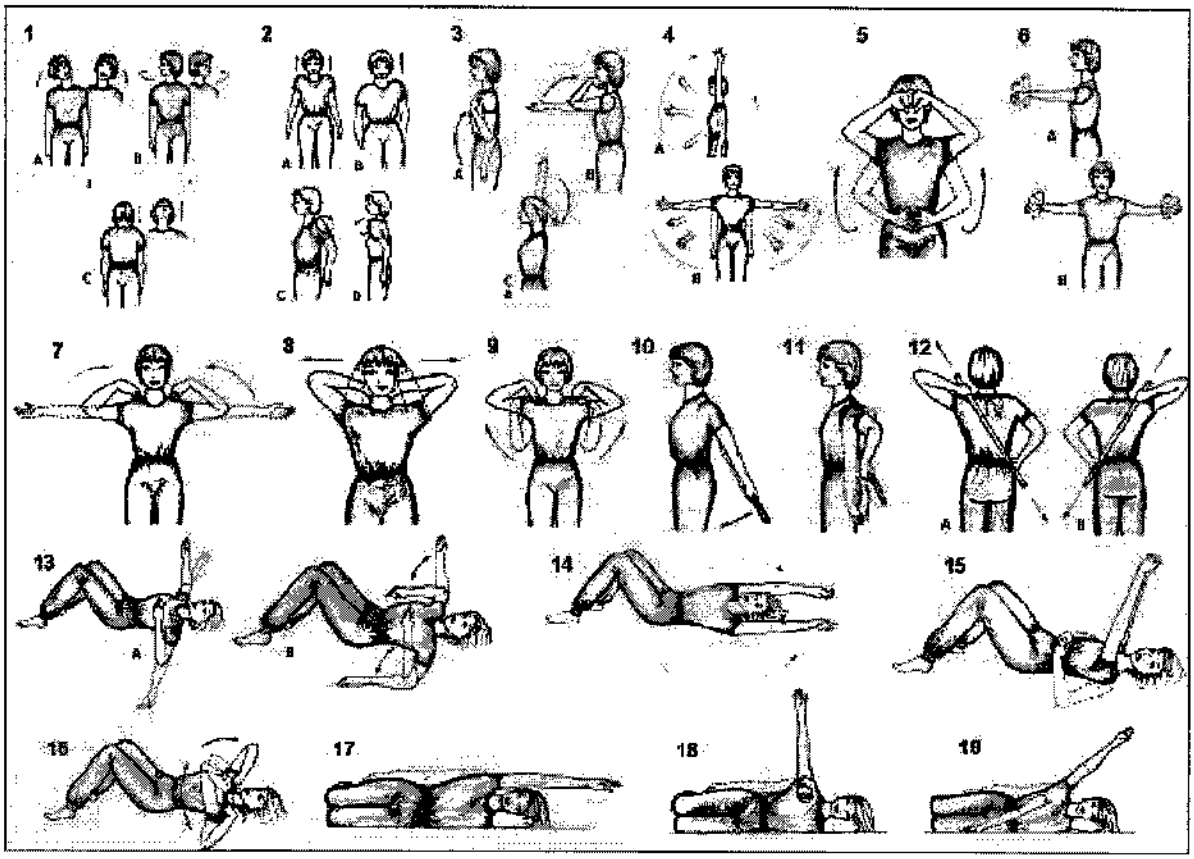

Figure 1: Physical therapy technique performed with 19 exercises

Table 2. Baseline Characteristics of the 89 patients

	N	ALND (n=31)	SNB With rehabilitation (n=30)	SNB without rehabilitation (n=28)	P
Age (years)					
Range	31 to 84	37 to 84	31 to 79	37 to 80	
95% central range	37 to 79.9	38.5 to 81.0	32.2 to 72.7	37.8 to 79.3	
Mean	55.5	56.5	52.3	57.2	
Median	12.5	55.0	49.5	56.5	0.29*
BMI (sd)	27.5 (5.8)	28.1 (4.5)	28.4 (6.1)	25.9 (6.9)	0.12*
Laterality					
right (%)	41 (46)	16 (52)	9 (39)	16 (59)	
left (%)	48 (54)	15 (48)	21 (61)	12 (41)	0.09**
Axillary metastases found					
zero (%)	71 (79)	15 (45)	30 (100)	28 (100)	*
1 to 3 (%)	13 (15)	13 (39)	0 (0)	0 (0)	
>=4 (%)	5 (6)	5 (16)	0 (0)	0 (0)	
Mean number of LN dissected (sd)		-	1.8 (0.9)	2.0 (1.0)	0.58*
Adjuvant chemotherapy	52 (58)	25 (81)	16 (53)	11 (39)	**<0.01****

*Sd = standard deviation; BMI= Body mass index; *Kruskal-Wallis test; **Chi-square with continuity correction*

Table 3. Differences in ROM between different time periods

	30 days x preoperative					
	ALND		**SNB with rehabilitation**		**SNB without rehabilitation**	
Measure	**Mean (sd)**	**p**	**Mean (sd)**	**p**	**Mean (sd)**	**p**
Flexion*	-12.4° (19.0)	**<0,01**	-1.5° (10.3)	0.45	-3.5° (7.3)	0.33
Abduction*	-24.1° (26.4)	**<0,01**	-4.9° (16.1)	0.13	-4.5° (1.5)	0.32
	6 months x 30 days					
	ALND		**SNB with rehabilitation**		**SNB without rehabilitation**	
Measure	**Mean (sd)**	**p**	**Mean (sd)**	**p**	**Mean (sd)**	**p**
Flexion*	4.2° (11.8)	0.06	2.8° (6.4)	**0.04**	1.2° (10.5)	0.58
Abduction*	11.6° (22.8)	**0.01**	0.5° (3.4)	0.92	1.9° (23.4)	0.70
	6 months x preoperative					
	ALND		**SNB with rehabilitation**		**SNB without rehabilitation**	
Measure	**Mean (sd)**	**p**	**Mean (sd)**	**p**	**Mean (sd)**	**p**
Flexion*	-7.3° (16.3)	**0.02**	1.5° (10.2)	0.48	-3.7° (21.7)	0.41
Abduction*	-11.5° (19.6)	**0.003**	-4.8° (20.8)	0.26	-2.9° (25.2)	0.58

*Sd = standard deviation; *T paired test*

Table 4 – Increase in circumference measures over time across study groups

	ALND				SNB with rehabilitation				SNB without
Measure	**Pre op**	**30 days**	**6 months**	**p**	**Pre op**	**30 days**	**6 months**	**p**	**Pre op**	**30**
Hand										
None	24 (77.4)	23 (74.2)	23 (79.3)	0.93	24 (88.9)	23 (85.2)	21(84)	0.97	20 (76.9)	21
0 to 5%	6 (19.4)	6 (19.4)	4 (13.8)		2 (7.4)	3 (11.1)	3 (12)		4(15.4)	3
5 to 10%	1(3.2)	2(6.5)	2 (6.9)		1 (3.7)	1 (3.7)	1(4)		2(7.7)	1
more than 10%	0	0	0		0	0	0		0	
Wrist										
None	28 (90.3)	28 (90.3)	25 (86.2)	0.33	25 (92.6)	27(100)	22 (88)	0.19	22 (84.6)	22
0 to 5%	3 (9.7)	3 (9.7)	1 (3.4)		2 (7.4)	0	3 (12)		3 (11.5)	2
5 to 10%	0	0	2 (6.9)		0	0	0		1(3.8)	1
more than 10%	0	0	1 (3.4)		0	0	0		0	
Forearm										
None	20 (64.5)	23 (74.2)	21(72.4)	0.87	21 (77.8)	23 (85.2)	21 (84)	0.81	17 (65.4)	18
0 to 5%	9 (29.0)	6 (19.4)	6 (20.7)		6 (22.2)	4 (14.8)	4 (16)		9 (34.6)	7
5 to 10%	2(6.5)	2 (6.5)	1 (3.4)		0	0	0		0	
more than 10%	0	0	1 (3.4)		0	0	0		0	
Arm										
None	20 (64.5)	11 (35.5)	21(72.4)	0.53	24 (88.9)	23 (85.2)	22 (88)	0.97	18 (69.2)	19
0 to 5%	8 (25.8)	13 (41.9)	6 (20.7)		3 (11.1)	3 (11.1)	2 (8.0)		7 (26.9)	6
5 to 10%	3 (9.7)	5 (16.1)	2 (6.9)		0	1 (3.7)	1 (4.0)		1(3.8)	
more than 10%	0	2 (6.5)	0		0	0	0		0	

SNB with rehabilitation = SNB + R; SNB without rehabilitation = SNB – R

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4. Discussão

É interessante notar que, após a cirurgia, todas as mulheres deste estudo, independentemente do tipo de cirurgia realizada e da participação ou não no programa de reabilitação, apresentaram melhora do bem-estar emocional. Embora as pessoas possam sofrer com situações negativas, um trauma pode representar um crescimento com uma re-interpretação positiva. Este crescimento pós-traumático pode melhorar as relações interpessoais, apreciação pela vida, força pessoal, mudanças positivas, além de proporcionar uma nova visão das prioridades da vida. Este crescimento é consciente e, no caso das mulheres diagnosticadas por câncer de mama, é relatado por 60% a 95% delas. É possível que ocorra um estresse e um crescimento simultaneamente, pois freqüentemente esta experiência representa uma nova fase da vida (Morril et al.,2008).

Historicamente, a reabilitação somente era buscada pelas pacientes no pós-operatório de câncer de mama se elas apresentassem um edema significante ou ombro paralisado. Ocasionalmente, aquelas que necessitassem de andador, muleta ou braçadeira, e evoluíssem para uma disfunção esquelética, instabilidade

na coluna ou problemas no membro superior, eram encaminhadas para assistência. Muitas mudanças ocorreram desde a década de 1980, quando os tratamentos de reabilitação eram direcionados às crises ou necessidades específicas do membro superior. A prática clínica moderna requer que a intervenção seja realizada em todos os estágios do câncer de mama, conforme necessário, incluindo educação, medidas preventivas, bem como restauração das funções (Gerber e Augustine, 2000).

A QV destas mulheres é afetada por fatores fisiológicos e psicossociais, embora, muitas vezes, ao receberem o diagnóstico sintam-se saudáveis e com bem-estar físico. Além disso, neste serviço, no momento do diagnóstico estas mulheres recebem as primeiras informações sobre a doença e o tratamento, além de contar com o apoio de profissionais especializados que farão parte do programa após a cirurgia, mesmo quando excluídas do programa de reabilitação pós-operatório. Essas mulheres serão provavelmente beneficiadas após a cirurgia por este programa, que inicialmente foca na ação educativa com recomendações em relação à mudança da imagem corporal, e auxílio na preservação ou restauração das rotinas diárias e manutenção da independência. Estendendo-se para a intervenção, o controle e prevenção do edema, tratamento da dor e disfunções do ombro passam a ser o foco principal. Portanto, a participação no programa de reabilitação permite que as mulheres operadas por câncer de mama focalizem a responsabilidade pela sua saúde e por um estilo de vida mais saudável e de maior qualidade. É provável que por este motivo as mulheres deste estudo já partiram de um escore relativamente alto em relação a uma população sem doença.

Com a forte influência dos fatores físico-funcionais, psicológicos e socioculturais na QV, instrumentos de avaliação são necessários para verificar as repercussões dos tratamentos (Cho et al., 2006). A popularização do conceito de QV exige cuidados para não banalizar a sua avaliação.

Os questionários aplicados para observar as repercussões do tratamento na QV devem ser, preferencialmente, específicos. Por esta razão utilizamos o FACT-B. A definição clara dos objetivos no planejamento do estudo permitiu a adequada seleção dos questionários sobre QV a ser aplicados, para que se pudesse contemplar aspectos de natureza multidimensional e a subjetividade das respostas. A análise simultânea dos diversos fatores de variada natureza contribuiu efetivamente para se obter o melhor seguimento destas mulheres após a cirurgia, uma vez que tais fatores têm influências e repercussões mais intensas nos primeiros anos subseqüentes ao diagnóstico da doença. O FACT-B contempla a abordagem de aspectos da QV relacionados diretamente com o câncer de mama (Brady et al., 1997).

Assim como a maioria dos estudos, os resultados deste estudo são concordantes com a teoria que a BLS está associada a menor morbidade do braço, em um seguimento a curto prazo. Não se deve concluir que estas mulheres devam ser excluídas do programa de reabilitação, abrangendo, portanto, todas as suas facetas. Já com relação às mulheres que realizaram LA, o programa de reabilitação, incluindo a fisioterapia, é essencial no pós-operatório, com resultados satisfatórios, diminuindo a morbidade do braço.

Na maioria dos estudos os prejuízos nos movimentos de flexão e abdução do ombro nos primeiros meses após a cirurgia são maiores entre as mulheres que fizeram LA quando comparadas àquelas que realizaram a técnica do BLS (Leidenius et al., 2005; Fleissig et al., 2006; Mansel et al., 2006). Leidenius et al. (2005) observaram restrição de movimento de flexão e abdução do ombro duas semanas após a cirurgia, quando comparado com as medidas pré-operatórias, em 45% das mulheres que realizaram BLS e em 86% das que realizaram LA. Entretanto, a recuperação desses movimentos é rápida, ocorrendo em cerca de três meses em ambos os grupos. No presente estudo, mesmo submetidas a um programa de reabilitação, mulheres que realizaram a LA apresentaram um déficit de flexão e abdução, que embora melhorasse após um mês - o que corresponde ao fim do programa - ainda permaneceu com seis meses após a cirurgia.

Em relação ao linfedema foram encontrados resultados semelhantes com a literatura, sempre com baixa incidência entre mulheres que realizaram a BLS (Schulze et al. 2006; Husen et al., 2006; Fleissig et al., 2006; Rietman et al., 2003). Purushotham et al. (2005) observaram que as mulheres submetidas à BLS apresentaram menor aumento no volume do braço após um e três meses, e na avaliação subjetiva do linfedema (presente/ausente). Rönkä et al. (2005) encontraram pequeno aumento na circunferência do braço em ambos os grupos um ano após cirurgia. Contudo, alguns autores chamam atenção em seus trabalhos para que, se somente fossem consideradas as mulheres que não receberam radioterapia, o risco de desenvolver linfedema após a BLS poderia ser insignificante (Rönkä et al., 2005; Schulze et al., 2006).

A variedade de técnicas de mensuração e de tratamento para o linfedema dificulta a comparação entre os resultados. Os métodos mais utilizados para avaliação desta complicação foram medidas das circunferências do braço e medidas volumétricas, porém tais formas de avaliação clínica objetiva não foram padronizadas, o que poderia confundir os resultados em estudos semelhantes (Leidenius et al., 2003; Rönkä et al., 2005; Schulze et al., 2006; Wilke et al., 2006). Neste estudo utilizamos a medida da circunferência comparativa entre o membro operado e o contralateral à cirurgia da mesma mulher em todos os momentos avaliados e não encontramos linfedema, independentemente da técnica realizada e da intervenção ou não da reabilitação. Talvez o tempo curto de acompanhamento possa explicar o não aparecimento desta complicação, que depende de um tempo maior de seguimento para ser melhor apurada.

Outra complicação analisada neste estudo foi a AWS, ainda pouco conhecida e que pode aparecer entre a segunda e terceira semana após a cirurgia. O posicionamento da paciente durante a LA e a retração tecidual causada na cirurgia são as possíveis causas da formação de coágulos de fibrina nas veias superficiais e capilares linfáticos. Composta por uma rede de dois ou mais cordões visíveis e palpáveis sob a pele axilar, pode passar pelo espaço cubital e ocasionalmente chegar até o polegar, acompanhada ou não de dor e restrição de movimento. Leidenius et al. (2003) constataram uma diferença significativa de AWS entre as mulheres que realizaram BLS e LA (20% e 72%, respectivamente). Após três meses de cirurgia, somente uma paciente em cada grupo ainda apresentava AWS residual, nas outras houve melhora espontânea. Neste estudo

observamos apenas dois casos de AWS acompanhados de dor, um no grupo que realizou LA e outro no grupo de BLS, que necessitaram de fisioterapia para regressão dos sintomas.

A técnica da BLS realça uma estratégia de abordagem com um grande benefício às mulheres operadas por câncer de mama, embora não isenta de complicações. Existe um trauma tecidual mesmo com a preservação dos linfonodos axilares, e a habilidade do cirurgião, conhecimento da técnica e dissecção de um ou mais linfonodos sentinelas podem aumentar o risco de complicações (Krynyckyi e Kim, 2004; Wilke et al., 2006).

O que ainda é escasso na literatura é a forma como se deve abordar as mulheres submetidas à BLS, já que mesmo com menor incidência as complicações existem. Não encontramos nenhum estudo enfocando e respondendo a questões específicas da reabilitação física, como identificar o momento ideal para iniciar a fisioterapia, o tipo, a freqüência e duração dos exercícios realizados nas mulheres que realizaram a BLS. O programa que propusemos para a mulher operada por câncer de mama pretende facilitar a reinserção em sua própria vida, a partir do contexto de sua cultura e de suas expectativas.

Embora a intervenção da equipe de reabilitação não ofereça, por si só, melhora na recuperação físico-funcional do ombro entre as mulheres que realizaram BLS, já que estas mulheres apresentam um déficit insignificante na amplitude do movimento do ombro, um programa bem estruturado pode oferecer informações e orientações, além de exercícios. Enfatizar e trabalhar também aspectos de

higiene, ferida cirúrgica, cicatrização, direitos sociais e aspectos emocionais podem favorecer de maneira positiva a QV destas mulheres (Sachs et al., 1980; Sachs et al., 1981; Rubin et al., 2003; De Rezende et al., 2005).

Resultados como a melhora da QV e diminuição da morbidade do braço em mulheres submetidas à LA, em um curto período de tempo, foram claros e suficientes para se recomendar a inclusão de um programa de reabilitação. Embora as mulheres que realizaram BLS, independentemente da reabilitação, não apresentaram melhora satisfatória na QV, excepcionalmente no bem-estar emocional, não podemos assegurar qual a melhor abordagem de uma equipe multidisciplinar nestes casos. Estudos mais amplos são necessários para acrescentar e melhorar os resultados obtidos por este estudo.

5. Conclusões

Nas mulheres que realizaram LA houve um déficit nas medidas da flexão e abdução do ombro com 30 dias e 6 meses após a cirurgia. Não houve déficit de qualquer movimento nas mulheres que realizaram BLS, independentemente do programa de reabilitação. Houve apenas dois casos de AWS durante o seguimento. Não houve aumento nas mediadas das circunferências nos diferentes pontos do membro superior ipsilateral à cirurgia em qualquer dos três grupos.

Nas mulheres que realizaram LA houve uma melhora na QV quanto ao bem-estar físico, funcional, emocional e subscala de mama após 30 dias de cirurgia, mantendo-se com seis meses apenas no emocional. Ns mulheres que realizaram BLS hndentemente da intervenção ou não de um programa de reabilitação.

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7. Anexos

7.1. Anexo 1 – Aprovação do CEP

FACULDADE DE CIÊNCIAS MÉDICAS
COMITÊ DE ÉTICA EM PESQUISA

www.fcm.unicamp.br/pesquisa/etica/index.html

CEP, 17/04/06.
(Grupo III)

PARECER PROJETO: Nº 111/2006 (Este nº deve ser citado nas correspondências referente a este projeto)
CAAE: 0075.0.146.000-06

I-IDENTIFICAÇÃO:

PROJETO: "AVALIAÇÃO DA QUALIDADE DE VIDA NAS MULHERES OPERADAS POR CÂNCER DE MAMA - TÉCNICA DA BIÓPSIA DO LINFONODO SENTINELA: INTERVENÇÃO FISIOTERÁPICA"
PESQUISADOR RESPONSÁVEL: Marcela Pouzio Pinto e Silva
INSTITUIÇÃO: Centro de Atenção Integral à Saúde da Mulher - UNICAMP
APRESENTAÇÃO AO CEP: 10/03/06
APRESENTAR RELATÓRIO EM: 28/03/07 (O formulário encontra-se no site acima)

II - OBJETIVOS

Avaliar a influência da fisioterapia na QV de mulheres submetidas à técnica da biópsia do linfonodo sentinela.

III - SUMÁRIO

A definição da amostra foi realizada considerando referencial teórico, com critérios bem definidos e metodologia adequada ao tipo de estudo a ser realizado. A instituição e pesquisador asseguram as condições necessárias para desenvolvimento da pesquisa.

IV - COMENTÁRIOS DOS RELATORES

Protocolo de pesquisa estruturado de forma adequada. O Termo de Consentimento Livre e Esclarecido está de acordo com a resolução 196/96.

V - PARECER DO CEP

O Comitê de Ética em Pesquisa da Faculdade de Ciências Médicas da UNICAMP, após acatar os pareceres dos membros-relatores previamente designados para o presente caso e atendendo todos os dispositivos das Resoluções 196/96 e complementares, bem como ter aprovado o Termo de Consentimento Livre e Esclarecido, assim como todos os anexos incluídos na Pesquisa, resolve aprovar sem restrições o Protocolo de Pesquisa supracitado.

O conteúdo e as conclusões aqui apresentados são de responsabilidade exclusiva do CEP/FCM/UNICAMP e não representam a opinião da Universidade Estadual de Campinas nem a comprometem.

VI - INFORMAÇÕES COMPLEMENTARES

O sujeito da pesquisa tem a liberdade de recusar-se a participar ou de retirar seu consentimento em qualquer fase da pesquisa, sem penalização alguma e sem prejuízo ao seu cuidado (Res. CNS 196/96 – Item IV.3.f) e deve receber uma cópia do Termo de Consentimento Livre e Esclarecido, na íntegra, por ele assinado (Item IV.2.d).

Pesquisador deve desenvolver a pesquisa conforme delineada no protocolo aprovado e descontinuar o estudo somente após análise das razões da descontinuidade pelo CEP que o aprovou (Res. CNS Item III 1.x), exceto quando perceber risco ou dano não previsto ao sujeito participante ou quando constatar a superioridade do regime oferecido a um dos grupos de pesquisa (Item V.3.).

O CEP deve ser informado de todos os eventos adversos ou fatos relevantes que alterem o curso normal do estudo (Res. CNS Item V.4.). É papel do pesquisador assegurar medidas imediatas adequadas frente a evento adverso grave ocorrido (mesmo que tenha sido em outro centro) e enviar notificação ao CEP e à Agência Nacional de Vigilância Sanitária – ANVISA – junto com seu posicionamento.

Eventuais modificações ou emendas ao protocolo devem ser apresentadas ao CEP de forma clara e sucinta, identificando a parte do protocolo a ser modificada e suas justificativas. Em caso de projeto do Grupo I ou II apresentados anteriormente à ANVISA, o pesquisador ou patrocinador deve enviá-las também à mesma junto com o parecer aprovatório do CEP, para serem juntadas ao protocolo inicial (Res. 251/97, Item III.2.e).

Relatórios parciais e final devem ser apresentados ao CEP, de acordo com os prazos estabelecidos na Resolução CNS-MS 196/96.

VII - DATA DA REUNIÃO

Homologado na III Reunião Ordinária do CEP/FCM, em 28 de março de 2006.

Profª. Drª. Carmen Silvia Bertuzzo
PRESIDENTE DO COMITÊ DE ÉTICA EM PESQUISA
FCM / UNICAMP

7.2. Anexo 2 – Termo de Consentimento

Avaliação da qualidade de vida das mulheres operadas por câncer de mama - técnica da biópsia do linfonodo sentinela: intervenção fisioterápica

Pesquisadora responsável: Marcela Ponzio Pinto e Silva

- Estou sendo convidada a participar desta pesquisa porque vou fazer cirurgia de câncer de mama no Caism - UNICAMP.
- Sei que responderei a 2 questionários sobre qualidade de vida contendo informações pessoais, farei medidas do movimento e volume do braço, avaliadas somente pela pesquisadora responsável, mantendo o sigilo da fonte destas informações.
- As participantes deste estudo serão divididas em dois grupos.
- Um grupo será das mulheres que farão a cirurgia de um quadrante da mama com retiradas dos gânglios axilares e fisioterapia após.
- O outro grupo será das mulheres que farão a biópsia do linfonodo sentinela com a preservação dos gânglios axilares, *sendo que poderei realizar a fisioterapia ou não.*
- Todas as mulheres serão acompanhadas pelo Serviço de Fisioterapia, fazendo avaliações periódicas antes da operação, depois de 42 dias da cirurgia, após a quimioterapia e 1 ano depois.
- Se eu quiser participar da pesquisa, me comprometo a comparecer no serviço de fisioterapia para realizar estas avaliações periódicas e a qualquer momento posso deixar de participar deste estudo, sem que isso prejudique meu tratamento.
- Sei também que serei sorteada e não poderei escolher de qual dos grupos irei participar, caso eu aceite entrar no estudo.
- Fui esclarecida quanto ao meu direito de não participar da pesquisa e de ser atendida no ambulatório sempre que necessário. A não aceitação na participação no estudo não implicará na perda dos direitos iniciais rotineiramente oferecidos pelo ambulatório.
- Em caso de dúvidas ou esclarecimento, tenho o direito de telefonar para a fisioterapeuta Marcela Ponzio Pinto e Silva no número 3788-9428 ou para o Comitê de Ética da UNICAMP no número 3788-8936. Sei que não serei paga para participar deste estudo.

Paciente_____

Fisioterapeuta que atendeu_____

Campinas,_____de_____de200_____

7.3. Anexo 3 – Lista de verificação

Quadrantectomia com linfadenectomia axilar	( ) sim	( ) não
Biópsia do linfonodo sentinela	( ) sim	( ) não
Mulheres com idade entre 18 e 70 anos	( ) sim	( ) não
Primeira cirurgia para câncer de mama	( ) sim	( ) não
Cirurgia realizada no Caism/ UNICAMP	( ) sim	( ) não

Critérios de exclusão

Cirurgia de mama bilateral	( ) sim	( ) não
Dificuldade de comunicação	( ) sim	( ) não

Pode participar do estudo?	( ) sim	( ) não
Vai participar do estudo?	( ) sim	( ) não

Se a mulher foi incluída no estudo:

HC:_____

Número na pesquisa: **( ) ALND** **( ) BLS 1** **( ) BLS2**

7.4. Anexo 4 – Carta de Autorização do FACT

----- Original Message -----
From: Luis Sarian
To: hmorrow@facit.org
Sent: Friday, March 25, 2005 2:01 PM
Subject: authorization to use questionnaires

Helen A. Morrow, MA
Manager, Business Operations FACIT

Dear Helen,

We work in the Universidade Estadual de Campinas (Campinas State University), shortly UNICAMP, a public institution that develops research in many fields. Our group is dedicated to research in gynecologic oncology and we are currently starting some other studies with breast cancer. The University hospital currently receives 350 new cases of breast cancer per year, approximately. We are now planning a study on the quality of life (QOL) of breast cancer patients that undergo surgical and systemic treatments. Our purpose is to assess QOL with the FACIT questionnaires, translated into Portuguese, along with other psychometric instruments such as the Hospital Anxiety and depression (HAD). Briefly, patients would be evaluated immediately before surgery, immediately after the procedure, during the course of their systemic (chemo/radiotherapy) treatment and one year after their treatment has been finished. We have a research partnership with Neli Muraki Ishikawa, that has been granted recently by you with a fee waiver. Similarly to her study, ours will be a completely academic project, conducted in a public hospital with patients that are treated without any financial charges. Unfortunately, we can not match the sums ($1.500, 00) proposed by the FACIT team for the use of the translated questionnaires. Therefore, we are submitting the FACIT translation requesting form, and kindly asking you and your team to waive this fee, as this is a non-profit project solely. We are looking forward to receiving your favorable response.

Yours sincerely,

Luis Otávio Sarian, MD
Sophie Derchain, MD, PhD
Universidade Estadual de Campinas

----- Original Message –
From: Helen Morrow
To: Luis Sarian
Sent: Wednesday, April 06, 2005 9:08 PM
Subject: Re: authorization to use questionnaires

Hello Luis Sarian:

Thank you for completing the Translation Request form. After reviewing your request, and speaking with Ben Arnold, Manager of the Translation Project, he has granted you permission to use the FACT-B in Portuguese for this study only, waiving the standard licensing fee normally associated with the use of translated questionnaires. I have attached a copy of the most current version of the FACT-B questionnaire (Version 4) in Portuguese for your review and possible use. With your agreement to a few simple requests, we ask that you review our user's agreement that can be found on our website at www.facit.org (See Requests & Registration: User's Agreement). Should you actually decide to include the questionnaire in your research, we would also request that you take the time to complete a Collaborator's Project Information Form on line to submit for our files. We are in the process of updating our website, so, many areas of the site are under construction. We appreciate your patience as we continue to create an efficient and user friendly site. Please keep in mind that the questionnaire has a copyright attached and can not be altered without strict permission from Ben Arnold. I have taken the liberty of attaching a few documents on the development and validation, including the raw scoring template of the FACT-Taxane that may be of assistance to you. Eventually these documents will be available on our website, but a fee will be associated with its access. Please accept them now with our compliments.

I hope you will find this information useful. If you have additional questions, please do not hesitate to contact me again.

Thank you and best of luck,

Helen A. Morrow, MA
Manager, Business Operations
www.facit.org
hmorrow@facit.org

----- Original Message -----

From: derchain@supernet.com.br
To: Helen Morrow
Sent: Tuesday,
December 20, 2005 12:49 PM
Subject: Re: authorization to use questionnaires

Dear Helen Morrow,

You and your team have, early this year, granted us permission to use the Portuguese version of the FACT-B. As agreed, we are currently using the Version 4 of the questionnaire, with success, in a prospective study protocol. However, because we have several cases of advanced breast cancer, which are treated with radical surgeries that include lymphadenectomy, lymphedema is a major concern to us. We would therefore kindly ask you to extend the permission to the use of FACT-B+4. The additional questions, regarding movement of the arm, will be very valuable to our research, and we would very much appreciate this new contribution from yours. To our knowledge, there is no Portuguese version of the last four questions in FACT-B+4. Should you grant us permission to use FACT-B+4, we will ask for professional assistance, here in Brazil, to appropriately translate and validate this portion of the questionnaire.

We are looking forward to receiving your response.
Yours sincerely,

Sophie Derchain

---------- Mensagem Original ----------
Assunto: Re: Fw: authorization to use questionnaires
De: "Helen Morrow" <hmorrow@facit.org>
Data: Ter,
Dezembro 27, 2005 4:03 pm
Para: derchain@supernet.com.br

Hello:

I was hoping to grant you permission to use the FACT-B+4 in Portuguese, but the scale has not been translated to Portuguese. At this time I am not aware of any plans to translate the scale. Please understand that you do not have permission to translate the scale independently. To do so would be in violation of the international copyright attached to the scale. We follow a strict methodology for translating the scale and require collaborators to follow those guidelines.

I am sorry for any inconvenience this may cause.

Thank you,

Helen
Helen A. Morrow, MA
Manager, Business Operations
www.facit.org
hmorrow@facit.org

7.5. Anexo 5 – FACT-B

Abaixo encontrará uma lista de afirmações que outras pessoas com a sua doença disseram ser importantes. Por favor, faça um círculo em torno do número que melhor corresponda ao seu estado durante os últimos 7 dias.

	BEM-ESTAR FÍSICO	**Nem um pouco**	**Um pouco**	**Mais ou menos**	**Muito**	**Muitíssimo**
GP1	Estou sem energia	0	1	2	3	4
GP2	Fico enjoado (a)	0	1	2	3	4
GP3	Por causa do meu estado físico, tenho dificuldade em atender às necessidades da minha família	0	1	2	3	4
GP4	Tenho dores	0	1	2	3	4
GP5	Sinto-me incomodado (a) pelos efeitos secundários do tratamento	0	1	2	3	4
GP6	Sinto-me doente	0	1	2	3	4
GP7	Tenho que me deitar durante o dia	0	1	2	3	4

	BEM-ESTAR SOCIAL/FAMILIAR	**Nem um pouco**	**Um pouco**	**Mais ou menos**	**Muito**	**Muitíssimo**
GS1	Sinto que tenho uma boa relação com os meus amigos	0	1	2	3	4
GS2	Recebo apoio emocional da minha família	0	1	2	3	4
GS3	Recebo apoio dos meus amigos	0	1	2	3	4
GS4	A minha família aceita a minha doença	0	1	2	3	4
GS5	Estou satisfeito (a) com a maneira como a minha família fala sobre a minha doença	0	1	2	3	4
GS6	Sinto-me próximo (a) do (a) meu (minha) parceiro (a) ou da pessoa que me dá maior apoio	0	1	2	3	4
Q1	*Independentemente do seu nível atual de atividade sexual, favor de responder à pergunta a seguir. Se preferir não responder, assinale o quadrículo [ ] e passe para a próxima seção*					
GS7	Estou satisfeito (a) com a minha vida sexual	0	1	2	3	4

FACT B

Por favor, faça um círculo em torno do número que melhor corresponda ao seu estado durante os últimos 7 dias.

	BEM-ESTAR EMOCIONAL	Nem um pouco	Um pouco	Mais ou menos	Muito	Muitíssimo
GE1	Sinto-me triste	0	1	2	3	4
GE2	Estou satisfeito (a) com a maneira como enfrento a minha doença	0	1	2	3	4
GE3	Estou perdendo a esperança na luta contra a minha doença	0	1	2	3	4
GE4	Sinto-me nervoso (a)	0	1	2	3	4
GE5	Estou preocupado (a) com a idéia de morrer	0	1	2	3	4
GE6	Estou preocupado (a) que o meu estado venha a piorar	0	1	2	3	4

	BEM-ESTAR FUNCIONAL	Nem um pouco	Um pouco	Mais ou menos	Muito	Muitíssimo
GF1	Sou capaz de trabalhar (inclusive em casa)	0	1	2	3	4
GF2	Sinto-me realizado (a) com o meu trabalho (inclusive em casa)	0	1	2	3	4
GF3	Sou capaz de sentir prazer em viver	0	1	2	3	4
GF4	Aceito a minha doença	0	1	2	3	4
GF5	Durmo bem	0	1	2	3	4
GF6	Gosto das coisas que normalmente faço para me divertir	0	1	2	3	4
GF7	Estou satisfeito (a) com a qualidade da minha vida neste momento	0	1	2	3	4

	SUB-ESCALA DE MAMA	Nem um pouco	Um pouco	Mais ou menos	Muito	Muitíssimo
B1	Sinto falta de ar	0	1	2	3	4
B2	Sinto-me insegura com a forma como me visto	0	1	2	3	4
B3	Tenho inchaço ou dor em um ou ambos os braços	0	1	2	3	4
B4	Sinto-me sexualmente atraente	0	1	2	3	4
B5	Sinto-me incomodada com a queda do cabelo	0	1	2	3	4
B6	Fico preocupada com a possibilidade de que outros membros da minha família um dia tenham a mesma doença que eu	0	1	2	3	4
B7	Fico preocupada com o efeito do "stress" (estresse) sobre a minha doença	0	1	2	3	4
B8	Sinto-me incomodada com a alteração de peso	0	1	2	3	4
B9	Consigo sentir-me mulher	0	1	2	3	4
P2	Sinto fortes dores em algumas regiões do meu corpo	0	1	2	3	4

7.6. Anexo 6 – FACT-B Scoring Guidelines (Version 4)

Instructions:* 1. Record answers in "item response" column. If missing, mark with an
2. Perform reversals as indicated, and sum individual items to obtain a score.
3. Multiply the sum of the item scores by the number of items in the subscale, then divide by the number of items answered. This produces the subscale score.
4. Add subscale scores to derive total scores (TOI, FACT-G & FACT-B).
5. **The higher the score, the better the QOL.**

Subscale	Item Code	Reverse item?		Item response	Item Score
PHYSICAL WELL-BEING (PWB)	GP1	4		-_____	=_____
	GP2	4		-_____	=_____
	GP3	4		-_____	=_____
	GP4	4		-_____	=_____
Score range: 0-28	GP5	4		-_____	=_____
	GP6	4		-_____	=_____
	GP7	4		-_____	=_____

Sum individual item scores: _____

Multiply by 7: _____

Divide by number of items answered: _____=**PWB subscale score**

SOCIAL/FAMILY WELL-BEING (SWB)	GS1	0	+	_____	=_____
	GS2	0	+	_____	=_____
	GS3	0	+	_____	=_____
	GS4	0	+	_____	=_____
Score range: 0-28	GS5	0	+	_____	=_____
	GS6	0	+	_____	=_____
	GS7	0	+	_____	=_____

Sum individual item scores: _____

Multiply by 7: _____

Divide by number of items answered: _____=**SWB subscale score**

EMOTIONAL WELL-BEING (EWB)	GE1	4	-	_____	=_____
	GE2	0	+	_____	=_____
	GE3	4	-	_____	=_____
	GE4	4	-	_____	=_____
Score range: 0-24	GE5	4	-	_____	=_____
	GE6	4	-	_____	=_____

Sum individual item scores: _____

Multiply by 6: _____

Divide by number of items answered: _____=**EWB subscale score**

FUNCTIONAL WELL-BEING (FWB)	GF1	0	+	_____	=_____
	GF2	0	+	_____	=_____
	GF3	0	+	_____	=_____
	GF4	0	+	_____	=_____
Score range: 0-28	GF5	0	+	_____	=_____
	GF6	0	+	_____	=_____
	GF7	0	+	_____	=_____

Sum individual item scores: _____

Multiply by 7: _____

Divide by number of items ans wered: _____=**FWB subscale score**

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Subscale	**Item Code**	**Reverse item?**		**Item response**	**Item Score**
BREAST CANCER SUBSCALE (BCS)	B1	4	-	_____	=_____
	B2	4	-	_____	=_____
	B3	4	-	_____	=_____
	B4	0	+	_____	=_____
	B5	4	-	_____	=_____
Score range: 0-36	B6	4	-	_____	=_____
	B7	4	-	_____	=_____
	B8	4	-	_____	=_____
	B9	0	+	_____	=_____
	P2	NOT CURRENTLY SCORED			

Sum individual item scores: _____

Multiply by 9: _____

Divide by number of items answered: _____=**BC Subscale score**

To derive a FACT-B Trial Outcome Index (TOI):

Score range: 0-92

_____ + _____ + _____ = _____=**FACT-B TOI**

(**PWB** score) (**FWB** score) (**BCS** score)

To Derive a FACT-G total score:

Score range: 0-108

_____ + _____ + _____ + _____= _____=**FACT-G Total score**

(**PWB** score) (**SWB** score) (**EWB** score) (**FWB** score)

To Derive a FACT-B total score:

Score range: 0-144

_____ + _____ + _____ + _____ + _____ = _____=**FACT-BTotal scor**

(**PWB** score) (**SWB** score) (**EWB** score) (**FWB** score) (**BCS** score)

*For guidelines on handling missing data and scoring options, please refer to the Administration and Scoring Guidelines in the manual or on-line at www.facit.org

7.7. Anexo 7 – Ficha de avaliação

Qualidade de vida e morbidade do braço após a biópsia do linfonodo sentinela no câncer de mama inicial: intervenção fisioterapêutica

1. IDENTIFICAÇÃO

? Data da Avaliação: /__/__/__ Número de Registro da Pesquisa: /__/__/

? Nome:_____

? Data de Nascimento: /__/__/__ Telefone:_____ Hc_____

? Endereço:_____ _____

? **Grupo controle (LA): quadrantectomia com linfadenectomia axilar**

? **Grupo (BLS): biópsia do linfonodo sentinela**

? **BLS 1– Sem intervenção** **BLS 2 Com intervenção**

2. EXAME FÍSICO

1. Goniometria do Membro Superior Direito e Esquerdo

Goniometria	PRÉ		30 dias		6 MESES		1 ANO	
Flexão								
Abdução								

2. Cirtometria do Membro Superior Direito e Esquerdo

Cirtometria	PRÉ		30 dias		6 MESES		1 ANO	
Mão								
Punho								
Braço								
Antebraço								

3. DADOS CIRÚRGICOS

? Data da Cirurgia: /____/____/____/

? Grupo controle: **LA** Grupo: **BLS**

? LA: número de linfonodos dissecados: /____/ Nível: /____/

? BLS: 1- tecnécio 2-azul patente 3- ambos

? BLS: número de linfonodos dissecados: /____/ Nível: /____/

? Intercorrências: 1-sim 2-não

? Mama operada: 1-Direita 2-Esquerda

4. DADOS PRÉ E PÓS-CIRÚRGICOS

? Peso: /____/ Altura: /____/ IMC: /____/

? Estadiamento Clínico: T /____/ N /____/ M /____ /

? Estadiamento Cirúrgico: T /____/ N /____/ M /____ /

? Número de linfonodos comprometidos: /____/

? Intervenção fisioterapêutica: 1- não 2- sim

? Radioterapia: /____/ sessões 1-adjuvante 2- coadjuvante

? Quimioterapia: /____/ ciclos 1-adjuvante 2- coadjuvante

? Membro que mais utiliza: 1- direito 2- esquerdo

? Hipertensão arterial sistêmica: 1- não 2- sim

? Cardiopatia: 1- não 2- sim

? Diabetes: 1- não 2- sim

? Doença do aparelho locomotor: 1- não 2- sim

5. DADOS SOCIODEMOGRÁFICOS

? Estado civil: |__| solteira |__| casada |__| amasiada |__| separada |__| viúva

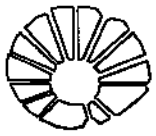
? Número de filhos vivos: |__|__|

? Trabalha e ganha salário: |__| não |__| sim

? Número de salários mínimos |__|

? Escolaridade: 1- analfabeto 2- I grau 3- II grau 4- III grau

7.8. Anexo 8 – Retornos



HC:

Nome:

"Qualidade de vida e morbidade do braço após a bisópsia do linfonodo sentinela no câncer de mama inicial: intervenção fisioterapêutica"

Comparecer para avaliações nos dias estabelecidos:

Após 1 mês ____/____/____

Após 6 meses ___/____/____

Após 1 ano ___/____/____

Fisioterapeuta: Marcela Ponzio Pinto e Silva

Caso você não possa comparecer por algum motivo,
por favor entre em contato com o nosso serviço : ✍ 3521- 9428
Muito obrigada pela sua colaboração!