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RISK MATTERS

Breast Cancer, Prophylactic Mastectomy and Critical Illness Insurance

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Every October is Breast Cancer Awareness Month around the world. This edition of Risk Matters takes the opportunity to discuss how current living insurance policies in Oceania provide valuable protection against this leading cancer among women worldwide but also highlights that critical illness insurance policies purposely do not cover surgical procedures undertaken in the absence of pre- surgically diagnosed disease to prevent future cancer.

Breast cancer in Australia

Breast cancer is the most common cancer among Australian women (excluding non-melanoma skin cancers) and the second leading cause of cancer death after lung cancer. More than 15,200 women and 120 men will be diagnosed with breast cancer in Australia this year with 60 being the average age of diagnosis. The annual number of new breast cancer diagnoses is expected to rise to 17,210 by 2020 or 47 cases each day. One in eight Australian women will develop breast cancer if she lives to age 85, and about 75% of all new breast cancers are diagnosed over the age of 50. The five-year survival rate is 89% in Australia, which is the best survival rate in the world. In 2009/2010 a total of 5,677 mastectomies were performed in females in Australian hospitals.[1] In 2005 dollars the total expected lifetime economic cost of breast cancer in NSW is $653,600 per person, comprising a financial cost $64,300 and burden of disease cost $589,300.[2]

Currently there is not sufficient knowledge of the causes of breast cancer and thus its early detection through regular mammograms and breast examination and improved treatment outcomes remain the best defence in the battle against breast cancer. BreastScreen Australia offers free mammograms to all women over 40, with a specific target group of ages 50-74. Under the Australian public health system, patients do not pay for a prophylactic double mastectomy, however, the waiting list is very long (e.g., three years). Even with private health insurance, the out-of-pocket expenses can be significant for a mastectomy, follow-up treatment and breast reconstruction. This is in addition to the lost productivity and lost income of the partner who may require time off work to care for their spouse and children.

Content

Breast cancer in Australia 1
Most common breast cancers 2
Genetic testing 2
Treatment 2
Prophylactic (preventative) mastectomy 3
Insurance cover 4
Case Study 5
Conclusion 6

Most common breast cancers

The majority (78%) of breast cancers are invasive ductal carcinoma, originating in the milk ducts that drain the milk, forming lobules of the of the breast tissue into the nipple. A further 11% of breast cancers are invasive lobular carcinoma (derived from the milk-producing glands or lobules), the remainder of breast cancers being a variety of differing histological subtypes.[3]

The age-standardised incidence rate of female breast cancer has remained fairly steady since 1995 at 110 to 118 per 100,000. Incidence rates for 50-69 year olds peaked in 2001, while those for aged 40-49 have increased slightly from 119 to 156 per 100,000 for the 27 years to 2008.[4]

Ductal carcinoma in situ (DCIS) is a pre-cancerous or non-invasive tumour of the breast, generally diagnosed by mammogram or found incidentally as a result of a biopsy for an unrelated lesion. In 2008, 1,700 Australian women were diagnosed with DCIS. The age-standardised incidence rate of DCIS has risen from 11 to 15 per 100,000 between 1997 and 2008. The DCIS rate for females younger than 50 has remained steady over that time.

DCIS is a risk marker for future breast cancer; women diagnosed with DCIS are four times more likely to develop a subsequent invasive breast cancer. The goal of therapy for DCIS is to prevent a future breast cancer. Because of this risk, currently DCIS is surgically treated with local excision (lumpectomy) and typically local radiotherapy and/or endocrine therapy. Lymph node biopsy to look for spread of disease and chemotherapy are not routinely performed as this condition is not an invasive cancer. Lobular carcinoma in situ accounts for only 5% of all breast carcinoma in situ, and compared to DCIS is not thought to reflect as high an increased future breast cancer risk.[5]

Breast cancers on observational studies can regress spontaneously. The overdiagnosis of breast cancers (i.e., detected and treated even though they would never cause problems if they were left alone) is reported to range from 10% to 50%.[6]

Genetic testing

Most breast cancers are sporadic. Less than 10% of all breast cancers are associated with germ line (present at birth) genetic mutations.[7]

BRCA1 and BRCA2 gene abnormalities were identified in the 1990s as predisposing to breast cancer. Possible BRCA mutation in a breast cancer survivor is suggested by:

- A family history of two or more first- or second-degree relatives with breast cancer
- Early onset of cancer (before age 40)
- A first-degree relative with breast cancer before the age of 50 years
- Personal history of ovarian cancer or first or second degree relative with ovarian cancer
- Male relative with breast cancer

In women who are BRCA1 positive, the lifetime risk of breast cancer is 65% (compared to 11% with normal BRCA genes) and risk of ovarian cancer is 40% (compared to 1.5%). More precise breast cancer risks for an individual will depend on age, number and age at diagnosis of affected family members and the exact nature of the fault in the gene.[8]

Whilst prophylactic mastectomy can dramatically reduce breast cancer risk in women carrying the BRCA gene, a perusal of the literature found no data signifying a reduced future breast cancer risk in the absence of the BRCA gene.

Individuals can obtain a genetic test specifically for the BRCA1 and BRCA2 mutation. Medicare, the national healthcare system in Australia, does not subsidise these tests. The lack of rebates or private health cover and subsequent cost therefore may deter some women from testing.

Treatment

Medical options to reduce breast cancer mortality in those with no history of personal breast cancer are currently confined to surveillance (regular clinical breast checks or regular imaging such as mammography, ultrasound and MRI scanning), risk reducing medical therapy (e.g., Tamoxifen) or prophylactic mastectomy.

Treatment options for breast cancer include breast-conserving surgery (lumpectomy) that involves removing the breast lump with surrounding normal breast tissue to ensure a good clearance. Historically, this has become much more common than total mastectomy, which is reserved for high-risk breast cancers. DCIS is also treated by breast-conserving surgery and often radiotherapy as well.

Typical Treatments by Stage of Breast Cancer

Stage 0 (non-invasive CIS): Lumpectomy or mastectomy and radiation, sometimes hormone therapy.

Stage I or II: Lumpectomy or mastectomy, radiation and often chemotherapy.

Stage III: Chemotherapy and radiation before or after mastectomy, underarm lymph nodes removed, often targeted therapy.

Stage IV or recurrent: Surgery, chemotherapy, radiation, hormone, other therapies.

Source: US National Cancer Institute

Surgery for invasive breast cancer is generally followed by radiation treatment to the remaining part of the breast. If there is evidence of lymph node involvement or high-grade disease or other high risk factors for recurrence or spread are present, chemotherapy is generally also given. On occasions chemotherapy is given with a high risk tumour confirmed on biopsy even before surgery and radiotherapy in a bid to "catch" any early metastasis before they have spread. Surgery and radiotherapy otherwise will delay systemic treatment with chemotherapy.

Approximately 80% of breast cancers contain receptors sensitive to the hormones oestrogen and progesterone; these hormones act to promote the growth of these breast cancer cells. The effects of the hormones can be reduced by modulating the oestrogen receptor with Tamoxifen, for example, or reducing the formation of oestrogen with oestrogen forming enzyme blockers, such as aromatase inhibitors.

Prophylactic (preventative) mastectomy

Risk-reducing or prophylactic (preventative) mastectomy is surgery to remove one or both breasts. As with any surgery, there are risks of infection, worse-than-anticipated cosmetic outcome, risks of anaesthetic, etc. Anxiety or depression can accompany a post-surgical disappointment in body image. Complication rates can be as high as 15%-20%.[9]

Bilateral prophylactic mastectomy has been shown to reduce the risk of breast cancer by at least 95% in women who have a deleterious (disease-causing) mutation in the BRCA1 gene or the BRCA2 gene. Actress Angelina Jolie significantly raised the profile of BRCA gene risk by announcing her double mastectomy at age 37 as a pre-emptive measure against breast cancer after testing positive for a BRCA1 mutation.

There is no consistent evidence in 2014 that in the absence of this gene that this surgery has any positive impact on survival. Despite this, due to significant anxiety suffered by some women with a strong family history (but BRCA negative) of breast cancer, prophylactic mastectomy has been offered in a bid to allay anxiety.

Even after a diagnosis of breast cancer in the BRCA negative patient, contralateral prophylactic mastectomy does not clearly improve survival. Despite this evidence, anecdotally contralateral prophylactic mastectomy (CPM) is on the increase in Australia as well as in the US For many, medical decision making is not always driven by logic; there may be a strong emotive component. Many women overestimate their actual risk for cancer in the unaffected breast.[10]

For women with single breast cancer, the overall risks for developing another breast cancer over the next 25 years are approximately 40% for BRCA1 carriers, 30% for BRCA2 carriers and 15%–20% for non-carriers. However, if a woman is younger than 40 years old at the time of her first breast cancer diagnosis, the cumulative risks over the next 25 years are higher at approximately 55% for BRCA1, 40% for BRCA2 and 25%–30% for a BRCA1/2-negative woman. These numbers are much lower for women who have a first breast cancer diagnosis after age 50.[11]

Whilst these recurrence figures appear high, currently there is insufficient proof for an overall survival benefit for most breast cancer patients who undergo a CPM, and no randomized trials have yet been performed.[12]

However, for patients with a deleterious BRCA1 or BRCA2 mutation, and in some studies, women diagnosed at a young age (<50 years), a survival benefit has been attributed to a CPM.

Tumour tissue genetic analysis (genomic testing) can assist with planning therapy. An example is Oncotype DX, a widely used genomic test by which interrogating 21 genes can provide specific information, such as:

- The likelihood that the breast cancer will return.
- An estimate of benefit from chemotherapy if treated for early-stage invasive (stage I or II) breast cancer.
- An estimate of benefit from radiation therapy if treated for DCIS (relatively new test).[13]

Note that a genomic test investigates specific genes expressed in the tumour tissue whereas the term "genetic testing" generally refers to an investigation of one's DNA carried in all cells of the body.

Unlike prostate cancer, which for low grade prostate cancers can have a program of active surveillance without immediate intervention, there is no current program or algorithm to follow in breast cancer treatment. Investigative trials to ascertain if some breast tumours can be safely monitored are sorely needed given the overdiagnosis rate of breast cancer as noted above.

Insurance cover

Having adequate cover for breast cancer under several types of life insurance policies can make a difference in alleviating financial stress.

- Income protection – Cancer patients may continue working through treatment but at less than full capacity, allows the individual to receive up to 75% of their income while taking time off work to recuperate from surgery and chemotherapy until able to return to full-time work. One Australian insurer reported breast cancer accounts for 20% of IP claims.[14]
- Total and permanent disability – This coverage provides a lump sum payment to repay debt and pay ongoing medical expenses if the individual is unlikely to be to work again. One Australian insurer reported breast cancer accounts for 18% of TPD claims.[15]
- Life cover – Cancers on the whole account for 56% of all female death claims on underwritten non-accelerated policies. Across both sexes cancers on the whole comprise 79% of all terminal illness claims.[16]
- Trauma or critical illness – This coverage provides a lump sum payment upon diagnosis at any stage, with many policy definitions providing partial payment on pre-cancerous stage and full payment when undertaking appropriate treatment. Receiving monies not tied to the ability to work gives flexibility to seek the best medical care, pay for expensive treatment, travel and accommodation costs associated with ongoing therapy, and repay debt. There are additional policy benefits, such as financial planning support and confidential counselling. If trauma insurance is considered too expensive, a lump sum benefit can still be accessed through the trauma benefit in a comprehensive IP policy. In Australia, New Zealand and England, breast cancer accounts for over 60% of all female trauma claims.[17]

Generally, a full payment is available upon diagnosis of invasive breast cancer and also upon total mastectomy for DCIS. These days many insurers recognise the different treatment options women have when diagnosed with breast cancer and extend cover with full payments for carcinoma in situ of the breast (where the tumour has not yet spread to surrounding tissue), which either results in one of two options:

- Removal of the entire breast.
- Breast conserving surgery (e.g., lumpectomy) with follow-up treatment (chemotherapy or radiotherapy).

The partial payments (e.g., 20% of sum insured with or without a dollar maximum) made on carcinoma in situ of the breast comes with added cost and its financial value is questionable except for the client's perception.

On the next page is a relevant case study in trauma cover.

Elsewhere the terms and conditions of the policy stipulate claim requirements including:

- Supporting evidence from appropriate specialist medical practitioners registered in Australia or New Zealand.
- Confirmatory investigations including, but not limited to, clinical, radiological, histological and laboratory evidence.
- If a trauma claim is a result of a surgical procedure, evidence that the procedure was medically necessary.

Case Study

The claimant is a 45-year-old woman who has a strong family history of breast cancer but was tested negative for the BRCA1 and BRCA2 mutation genes. She underwent regular screening for breast cancer, which indicated a negative result, but due to her strong family history the claimant suffered significant anxiety that she would develop breast cancer. She consulted several oncologists and surgeons to ascertain her best options in the prevention of breast cancer. The claimant ultimately elected to undergo a bilateral prophylactic mastectomy.

The breast tissue was sent to pathology for histological examination. The histology report noted the possible presence of DCIS in the right breast. The word "possible" is used because several pathologists reviewed the histology report and not all were in agreement that it was DCIS rather than atypical ductal hyperplasia. However, following some debate it was decided that given the strong family history of breast cancer, it was "more likely to be" DCIS.

The claimant holds a trauma insurance policy covering malignant cancer at 100% sum insured defined as follows (only the relevant exclusions reproduced):

"Malignant cancer means the presence of a malignant tumour, including leukaemia, malignant lymphoma and other haemopoietic malignancies.

The tumour must be confirmed by histological examination and:

- *the life insured must require major interventionist therapy including surgery, radiotherapy, chemotherapy, biological response modifiers or any other major treatment, or*
- *the tumour must be sufficiently advanced such that major interventionist therapy is no longer recommended*
- *The following cancers are specifically excluded:*
- *all cancers described as carcinoma insitu. Carcinoma in situ of the breast is covered only if it requires:*
  - » *the removal of the entire breast or*
  - » *breast conserving surgery and radiotherapy or*
  - » *breast conserving surgery and chemotherapy (chemotherapy means the use of drugs specifically designed to kill or destroy cancer cells)*

Carcinoma in situ of the breast treated by breast conserving surgery and other forms of adjuvant systemic therapy, including endocrine manipulation therapy, hormonal manipulation therapy or non-endocrine adjuvant therapy, is not covered."

If one accepts the diagnosis of carcinoma in situ, as was true in this instance, then further consideration is needed as to whether the second part of the malignant cancer definition has been satisfied. This means treatment was required involving any of the following:

- the removal of the entire breast
- breast conserving surgery and radiotherapy
- breast conserving surgery and chemotherapy

As the claimant had undergone a bilateral prophylactic mastectomy as a preventative measure given her strong family history of cancer, and not to treat a diagnosed cancer, the insurer was challenged when adjudicating this claim.

An independent report was sought from an associate professor in breast surgery. He reported:

- The clinical diagnosis is right DCIS.
- The claimant has undergone a mastectomy and no further treatment is necessary.
- If the claimant had not already had the mastectomy, then appropriate treatment for the DCIS could consist of local wide excision alone, or local wide excision followed by radiotherapy or chemotherapy. All of these treatments are reasonable following discussion with the patient.
- Bilateral prophylactic mastectomy is not "required" treatment but certainly is an option to be discussed.

The insurer declined the claim for full payment on the basis the claimant did not meet the second part of the policy definition. However, a partial trauma claim was paid for diagnosis of carcinoma in situ). Reliance is placed on a "requirement" for the treatment and in this instance the independent medical opinion was the mastectomy was not "required".

In the UK some critical illness insurers deal with similar situations by specifically mentioning in their policy terms and conditions that they will not cover "prophylactic mastectomy or lumpectomy without histological evidence of carcinoma in situ".

Conclusion

The rising incidence of diagnosed cancer and growing public awareness of screening have increased the number of early diagnoses of many cancers including breast cancers.

The critical illness policy definition for malignant cancer, and specifically carcinoma in situ, does not take into account such factors as family history of cancer and the ongoing anxiety an individual may have around the actualisation of that cancer. As the above case illustrates, an individual may undertake a procedure in response to her risk factors of history and feelings of anxiety. Critical illness insurance policies require claimants to first show proof of histological diagnosis, followed by the undergoing of medically necessary specified surgery or treatment.

Rightly or wrongly, the existence of insurance may influence the choice of treatment to qualify for claim payment. On balance critical illness insurance providers are not yet convinced there is a need to cover medical preventative measures for diseases one does not yet have and view carcinoma in situ as fully treatable with minimal intervention and cost. Those expenses should be met by private health insurance, medical scheme or hospital cash plans. A few trauma insurers have taken the position that treatment for non-invasive carcinoma in situ are just as onerous and expensive as those for more advanced stages of cancer, and the diagnosis may be no less emotionally devastating. They offer to pay out lower sums insured for early stage cancers than more advanced cancers, either as an add-on cover or as part of comprehensive coverage with different tiers commensurate with the cancer severity.

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Endnotes

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