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Resource implications of risk-reducing mastectomy and reconstruction



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Abstract

Aim: Risk-reducing mastectomy (RRM) is on the increase, now frequently combined with breast reconstruction (BR). However, the resource implications associated with bilateral mastectomy and reconstruction are unknown. This study assessed the overall cost of performing risk-reducing surgery.

Methods: All cases of RRM and BR performed between 1991 and 2011 at this hospital were identified from a prospectively collected database. All patients undergoing bilateral mastectomy were included, when at least one mastectomy was risk-reducing. Overall treatment costs for all surgical procedures, complications, revisional procedures and outpatient attendances were calculated and compared to the National Tariff allowed. Mann–Whitney *U* and Fischer's exact tests were used to calculate levels of significance.

Results: Fifty patients underwent bilateral mastectomy and BR (median follow up 20 [range 1-106] months), 72 were Latissimus Dorsi reconstructions (LDR) and 28 were Subpectoral reconstructions (SPR). LDR took longer than SPR (p = 0.001), with a greater length of stay (p = 0.024). Nine percent of patients returned to theatre for early complications, but the type of BR did not influence the early complication rate (LDR *versus* SPR, p = 0.345) or the need for additional unplanned procedures (LDR *versus* SPR, p = 0.671). The overall mean cost for bilateral RRM and BR was £14,797 per patient. The inpatient cost for bilateral RRM and LDR was £10,082 compared with £5,905 SPR. Both procedures exceeded the £5,697 tariff allowed in the UK.

Conclusion: Bilateral RRM and BR is a safe procedure, but the resource implications are considerable and exceed the tariff allowed, particularly when performing more complex techniques.

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Keywords: Risk reducing mastectomy; Breast reconstruction; Cost

Introduction

More risk-reducing mastectomies (RRM) are being carried out as a result of greater knowledge of genetic risk factors, evidence of benefit, a rising demand, and wider availability.^{1–7} Indications for RRM include a strong family history of breast cancer, BRCA1 and BRCA2 mutations, and a personal history of breast cancer. RRM is an effective strategy both for those with a previous history of breast cancer (contralateral RRM) and for those at high genetic or familial risk (bilateral RRM), reducing risk by up to 95%.^{7–15} Women often request immediate breast reconstruction (BR) at the time of mastectomy, as this has both psychological and aesthetic benefits^{16,17} but bilateral RRM and immediate

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http://dx.doi.org/10.1016/j.ejso.2015.10.002 0748-7983/© 2015 Elsevier Ltd. All rights reserved. BR is a major, labour-intensive procedure which is associated with a significant period of recovery. Moreover, the majority of patients will subsequently require further surgical procedures.¹⁸

The combined costs of RRM and immediate BR, together with any further revisional surgery are considerable. Currently risk-reducing surgery is routinely funded in the UK by the National Health Service (NHS). Other breast procedures such as breast reduction or surgical correction of gynaecomastia are funded only when strict criteria are met. 'Payment By Results' (PBR) was a new system of funding which was introduced in 2002 as part of NHS reforms in the UK, now known as the NHS National Tariff Payment System.¹⁹ PBR changed the funding framework so that hospitals are paid for each patient's admission, and this admission is coded according to the activity generated by the admission and charged accordingly. Tariffs are set at a rate that encourages high quality care and which promotes efficiency. This means that the actual cost to the hospital of performing a given procedure may exceed the tariff received for it. This is relevant to riskreducing surgery, as a recent study has disclosed a shortfall in funding for bilateral mastectomy with autologous reconstruction, because a bilateral procedure attracts the same tariff as a unilateral case. Secondly, BR varies in its complexity, and although differing levels of skill and resources are required, reimbursement is often the same.²⁰

Healthcare spending is under intense scrutiny worldwide. Despite the recent global economic downturn, an increasing proportion of Gross Domestic Product (GDP) in Organisation for Economic Cooperation and Development (OECD) countries is now being spent on healthcare, in order to try and meet the increasing demands placed upon healthcare systems. The sustainability of this in Europe has been carefully reviewed in several recent reports^{21,22} and a key reform recommendation is the enablement of strategic resource allocation to ensure that health resources match health needs. However, there has been no attempt to cost risk reducing mastectomy and reconstruction. The aim of this study was to assess the resource implications of providing an 'in house' oncoplastic service for RRM and BR at a District General Hospital, in relation to the level of funding provided by the NHS in the UK.

Patients and methods

An analysis was carried out of all patients who underwent RRM and BR over a 20 year period (1991–2011) at The Royal Hampshire County Hospital, Winchester, UK. Patients were identified from a prospectively collected Unit Database, and the study included all patients treated by bilateral mastectomy, with at least one mastectomy being risk-reducing. Patients who had bilateral breast cancer were excluded. Indications, patient and operative details, complications, secondary procedures and outpatient attendances were recorded.

The overall treatment cost was calculated retrospectively, based on the present day costing of providing the same service, rather than historical pricing. This included the cost of the index procedure (bilateral RRM and BR), together with the pre- and post-operative outpatient costs, and any secondary procedure costs. The index procedure cost included the use of the operating theatre, the hospital stay, implants, transfusion, and all pathology costs. The finance department confirmed the hourly rate for theatre, including all theatre staff. Outpatient costs included all investigations carried out (for example, mammography or MRI). All implant use was recorded, and current prices were used to calculate the overall cost of implants both for the initial reconstruction and any subsequent replacements.

Mann–Whitney U and Fischer's exact tests were used to determine statistical significance. Results were considered significant when p < 0.05.

Results

Fifty patients underwent bilateral RRM and BR (mean age 45 [27–67] yr). Seventy eight percent were <50yr (Table 1). A steady rise in demand was observed during the study period, with over half of the patients undergoing surgery since 2006 (Fig. 1). Genetic risk (44%) and familial risk (44%) were the leading reasons for RRM (Fig. 2). Women with a genetic risk were younger than those with a familial risk (genetic risk, 40 [27–50] yr *versus* familial risk, 48 [31–60] yr, p = 0.001). All remaining patients without a genetic predisposition or a family history who underwent RRM had a previous history of breast cancer. Patients had little co-morbidity, the commonest risk factor being a history of smoking (Table 1). 28 patients were referred from the local population, whilst 22 patients were extra-regional referrals.

Of 100 procedures performed in 50 women, 70 of the mastectomies were RRM and 76 of the BRs were immediate. Sixty-six percent were bilateral mastectomies (BM)

Table 1 Patient demographics.

Demographic	Number of patients
Age < 30	5
Age 31–40	12
Age 41–50	22
Age > 51	11
BMI > 30	6 (SP = 2, LD = 4)
DM	0
Smoker	14 (SP = 6, LD = 8)
Ex-smoker	3 (SP = 1, LD = 2)
ASA III/IV	0

SP = Subpectoral Reconstruction, LD = Latissimus Dorsi Reconstruction, DM = Diabetes Mellitus, BMI = Body Mass Index, ASA = American Society of Anaesthesiologists.

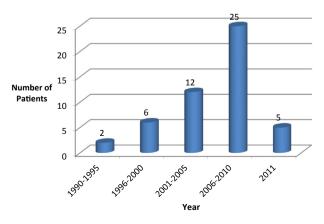
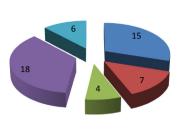


Figure 1. Workload over time.



 BRCA 1/2 with no personal history of breast cancer BRCA 1/2 with a personal history of breast cancer
FHx with no personal history of breast cancer
FHx with a personal history of breast cancer

A personal history of breast cancer with no FHx and BRCA -ve

FHx = Family History

Figure 2. Indications for surgery.

with bilateral immediate BR (IBR), 22% were BM with bilateral delayed BR (DBR) and 12% were BM with IBR on one side and DBR on the other side. Reconstruction was carried out either using a Latissimus Dorsi technique (LDR) combined with an implant or an expander (LDR, n = 72), or by a Subjectoral technique (SPR), using an implant or expander (SPR, n = 28). The indication for the method of reconstruction was principally patient choice, after a full discussion of the advantages and disadvantages of all the reconstruction techniques available, either at this unit or elsewhere. No Acellular Dermal Matrices were used in this series. Free flap reconstructions were excluded from this series, as these patients were referred to a regional unit performing microsurgery. The ratio of IBR to DBR was the same (4-1) for each reconstruction technique, and so the surgical operating times are comparable between techniques. All IBRs were performed using either a skin-sparing mastectomy technique (n = 63)or a Wise pattern skin-reducing mastectomy technique (n = 13). The main reason for DBR in this series was a history of previous breast cancer on the same or contralateral side, or patient request. LDR took twice as long as SPR (LDR versus SPR, 6.5 [2.5-9.0] hr versus 3.3 [1.5-6.1] hr, p = 0.001). Patients also experienced a longer postoperative stay following LDR (LDR versus SPR, 7 [3-13] days versus 6^{1-19} days, p = 0.024). There was typically only one surgical team performing bilateral cases, lead by a consultant oncoplastic surgeon.

Eighteen percent of patients (9% of reconstructions) in this series developed major complications which required an unscheduled return to theatre, including flap loss, infection, skin necrosis and haematoma formation (Table 2). The proportion of patients developing early complications before discharge or requiring unplanned procedures after discharge, such as implant exchange or capsulectomy, was the same in both groups (early complications: LDR 11% versus SPR 3.5%, p = 0.345, unplanned procedures: LDR 50% versus SPR 57%, p = 0.671). Planned

Table 2
Complications.

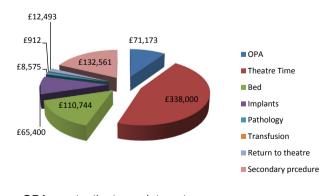
I contraction			
Complication requiring return to theatre	SP	LD	Total
Flap loss	0	1	1
Implant infection requiring removal	0	2	2
Skin necrosis requiring debridement	1	1	2
Haematoma requiring evacuation	0	3	3
Donor site infection requiring drainage	0	1	1
Total	1	8	9 (9%)

SP = Subjectoral Reconstruction, LD = Latissimus Dorsi Reconstruction.

procedures such as nipple reconstruction were carried out more frequently following LDR (LDR 80% versus SPR 50%, p = 0.005) (Table 4). One patient required revisional surgery to convert bilateral SPR to bilateral Transverse Upper Gracilis flap reconstruction.

The overall costs of procedures, including theatre time, hospital stay, outpatient attendances, implants, pathology, transfusion, return to theatre and secondary procedure costs are summarized in Fig. 3. The mean cost of bilateral RRM and BR for this entire series taken as a whole was £14,797 per patient, with theatre time being the most costly item $(\pounds 1,200/hr, 46\%)$ of the overall cost). Hospital stay was priced at £318 per 24hrs for a ward bed and £774 for a bed in HDU, but only 1 patient required HDU admission following LDR complicated by haematoma formation. Inpatient costs for bilateral mastectomy and bilateral BR depended on the reconstructive technique used (LDR £10,082 versus SPR £5,905), although the tariff received by the hospital was the same for each technique $(\pounds 5,697)$, and was also the same for unilateral and bilateral procedures. Additional theatre time required for LDR was the key factor responsible for the higher cost of this procedure.

The total follow up period for this study was 1,040 months, with a median follow up of 20 months per patient and a range of 1-106 months. Follow up care for these patients was labour-intensive, requiring >7 outpatient visits for consultation, aspiration, tissue expansion etc (Table 3). Although these visits were included in the overall cost



OPA = outpatient appointments

Figure 3. Procedural costs.

Table 3 Outpatient attendances.

Surgery	Outpatient appointments	BCN appointments	Seroma aspirations	Implant inflations	Total
SP	53 (3.8)	48 (3.4)	5 (0.4)	36 (2.6)	101 (7.2)
LD	104 (2.9)	164 (4.5)	56 (1.6)	63 (1.75)	268 (7.4)

SP = Subpectoral Reconstruction, LD = Latissimus Dorsi Reconstruction, BCN = Breast Care Nurse. Figures in brackets = Mean number per patient.

Table 4

Planned and unplanned secondary procedures.

Secondary procedures		Number of patients		
		SP	LD	
Planned	Nipple reconstruction	5	25	
	Port removal	5	16	
	Nipple tattoo	5	16	
Unplanned	Revision of nipple reconstruction	0	3	
	Repeat nipple tattoo	1	3	
	Implant exchange	6	16	
	Capsulotomy/ectomy (same implant re-used)	1	3	
	Repeat implant exchange	1	6	

SP = Subjectoral Reconstruction, LD = Latissimus Dorsi Reconstruction.

analysis, the costs of routine breast cancer follow up were not. Five patients with a past history of breast cancer developed local or distant recurrence during follow up, two of whom died, reflecting the high risk nature of the group. None of the patients choosing bilateral RRM developed a new breast cancer during follow up, supporting the effectiveness of risk-reducing mastectomy.

Discussion

The popularity of RRM is increasing. Data from the USbased Surveillance, Epidemiology and End Results (SEER) Cancer Registry has disclosed that the use of RRM more than doubled in patients with invasive breast cancer between 1993 and 2003, from 1.8 to 4.5%, and increased from 2.1% to 5.2% between 1998 and 2005 in patients with in situ disease.⁶ The current study has demonstrated an exponential increase in the use of RRM, rising from 2 cases between 1990 and 1995 to 25 cases between 2006 and 2010 (Fig. 1). A similar increase in RRM in patients with a past history of breast cancer has been reported in New York State.³ Several hospital-based studies also report greater use of RRM in the US, with rates rising from 6.5 to 16.1% at Ohio State University between 1999-2007⁴ and from 0 to 20% at the Mayo Clinic between 2000-2008.⁵ Our RRM mastectomy and reconstruction workload of 100 over 20 years compares very favourably with other units providing this service. For example, it amounts to 20% of the total number of risk-reducing mastectomies carried out for the whole of Norway between 1982 and 2009.²³ The gradual increase over time shown in Fig. 1 probably reflects the gradual rise in demand, the greater knowledge of genetic risk factors and the increasing evidence of benefit over this timeframe.

The effectiveness of RRM has been confirmed by a number of studies. Firstly, for patients without a history of breast cancer. Hartmann's group were the first to report that RRM resulted in a 90% risk reduction in women from high risk families.⁹ Secondly, the Rotterdam group subsequently demonstrated the effectiveness of RRM in 358 BRCA1/2 mutation carriers, with no patients developing breast cancer at a mean follow up of 4.5 years.¹ Pooled data from 10 European centres involving 550 women undergoing bilateral RRM confirmed a risk reduction of 90–95%, at a follow up of 3,334 women years.¹³ Moreover, a Cochrane systematic review concluded that RRM is effective in reducing the incidence of breast cancer but that there is still insufficient evidence that RRM improves survival.¹¹ Furthermore, for patients with a previous history of breast cancer, RRM reduces subsequent breast cancer by 94.4% and 96% in pre- and post-menopausal women, respectively,⁸ and may reduce subsequent breast cancer mortality.¹⁴ Lastly, a recent multicentre retrospective analysis of 390 BRCA carriers who developed stage I or II breast cancer has shown a survival advantage at 20 years follow up in those women undergoing contralateral RRM.¹⁵ The multivariate analysis showed a 48% reduction in death from breast cancer in the contralateral RRM group (hazard ratio 0.52, 95% confidence interval 0.29-0.93: p = 0.03). However, further research is required to confirm these findings. In the current series, of the 35 women without a past history of breast cancer, none went on to develop the disease. Whilst 5 of the 15 patients with a past history of breast cancer developed local or distant recurrence, none developed a new primary tumour. This supports the effectiveness of RRM.

The cost per patient in this series was calculated for the group as a whole, but only 70 mastectomies were purely risk reducing (in women with no previous history of breast cancer). Sixty-six percent of the group underwent bilateral RRM and immediate breast reconstruction, whilst 22% had bilateral mastectomy with bilateral delayed breast reconstruction, and 12% bilateral mastectomy with immediate reconstruction on one side and delayed reconstruction on the other. Although it could be argued this is a fairly heterogenous group, it has been analysed together as it reflects actual real life NHS practice and is typical of the cross-section of women requesting risk-reducing surgery. The heterogenous database reflects an exponential increase in demand, also reported by Hagen *et al.*

Developing a service for RRM has significant resource implications. When bilateral RRM and BR are performed

simultaneously in the UK, the level of reimbursement which can be claimed by the hospital is identical to the level of reimbursement for unilateral surgery. Although a bilateral procedure attracts an extra code (Z94.1), this has no impact on the level of reimbursement, making bilateral surgery less financially attractive to the hospital. Furthermore, a mastectomy done prior to a delayed BR attracts a higher level of reimbursement, because the combined tariff for a mastectomy followed by delayed BR is greater than tariff for the combined procedure the single (mastectomy = JA07C = $\pounds 2,030$, BR with subjectoral implant = $JA05 = \pounds 4,727$, mastectomy with immediate BR with subpectoral implant = $JA16Z = \pounds 5,697$). Immediate BR has both psychological and aesthetic benefits when compared to delayed reconstruction.^{16,17} It also has financial benefits for the NHS in the UK, which is publicly funded through a system of taxation, as IBR avoids repeated costly admissions and duplicated periods of recovery. The majority of the cost for carrying out RRM in our patients was for theatre time (£338,000) and for bed occupancy (£110,774) (Fig. 3). LDR was more time consuming than SPR because of more lengthy procedures and a longer hospital stay and should therefore attract a greater tariff. The current framework used to calculate reimbursement for RRM therefore acts as a financial disincentive for Units wishing to offer bilateral or more complex procedures. As Private Health Insurance schemes in the UK will not reimburse any risk-reducing procedures, the burden of funding is the responsibility of the NHS.

One limitation of this series is that it has considerably more LDRs than SPRs, which may not be representative of the move towards more implant based IBRs in modern day practice. However, LDR is still a very popular and robust flap-based reconstruction technique, and a "workhorse" in many oncoplastic surgeons' repertoire. The use of LDR accounted for 50% of all techniques, compared with SPR in only 30% of patients, in the recent UK National Mastectomy and Reconstruction Audit (NMBRA) of over 5,000 cases.²⁴ Furthermore, it may offer the additional advantages of a more realistic feeling breast and arguably requiring less revisional surgeries over the years compared to implant based techniques.

The length of hospital stay was 7 days following LDR and 6 days following SPR which is longer than expected when compared with modern day practice. Nearly half of our patients were referred from other regions, requiring longer hospital stays. More lengthy inpatient convalescence was commonplace in the 1990s.

This data in this series is original and accurate, being carefully recorded prospectively within the unit over a considerable period of time by the senior author for the purpose of audit. This ensured that cases were not missed from the analysis. All activity relating to each admission and outpatient attendance was recorded and cross-referenced with the hospital records and case notes to ensure accuracy. To avoid the confounding factor of changing costs over time, we have used current cost estimates, rather than relying on historical costs. This also makes the findings more relevant to present day practice. However, the surgical techniques and complications have remained largely unchanged over this timeframe, as they have been performed by two consultant surgeons (RMR and subsequently SL) using established techniques.

The series has highlighted the significant underfunding of bilateral procedures and more complex breast reconstruction, which has previously been reported for bilateral autologous breast reconstruction.²⁰ Although complex procedures are initially more costly, with time they may become relatively less expensive, as they require fewer revisional procedures.²² Our study has shown that LDR is initially more expensive than SPR (LDR £10,082 *versus* SPR £5,905), but longer follow up is required to address this important aspect of risk-reducing surgery.

Health economics are complex and multifactorial. However, possible solutions to this underfunding issue might include a greater tariff for bilateral, longer and more complex procedures. Alternatively, there may be a move towards less expensive reconstruction techniques, but caution must be exercised, as women requesting RRM are often young and should have the opportunity to choose procedures which offer the best long-term results.

Complication rates in our patients were low, comparing favourably with rates reported in the NMBRA.²⁴ Complications in this series requiring intervention developed in 11% of LDR *versus* 3.5% of SPR procedures, compared with 15.5% of LDR *versus* 11% of SPR procedures reported in the NMBRA. Furthermore, the implant loss rate at 3 months was low (2% this series *versus* 8.9% NMBRA). The higher early complication rates reported following more complex procedures such as LDR are counterbalanced by fewer long-term complications, better aesthetic results and improved quality of life.^{18,25,26} Patients also report greater aesthetic, physical, emotional and sexual well being 18 months following LDR when compared with SPR.²⁴

This study has focussed on the challenges of providing a risk-reducing strategy within the UK's publicly funded NHS system. However, our findings, including the surgical procedures carried out, the complications and the further procedures required, should be broadly applicable to surgeons around the world.

Conclusions

This study confirms that risk-reducing surgery is an effective and increasingly common intervention for high risk women. It can be carried out with low post-operative complication rates in a District General Hospital setting, by surgeons with sufficient training, and a referral-base which allows the development and maintenance of a range of skills. Further unplanned surgical procedures are required in >50% of patients undergoing implant-based

techniques, with or without the use of LD flaps. Reconstruction with LD is more time-consuming and costly compared with implant-only techniques, but both attract inadequate levels of reimbursement in the UK. More mature data is required to determine the longer-term clinical, aesthetic and patient-reported outcomes of different reconstructive procedures, and hence their future role in clinical practice. The gap between rising demand and the funding available for risk-reducing surgery will become an increasing cost pressure for the NHS and other healthcare systems with finite human and financial resources.

Conflict of interest

None declared.

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