Quality improvement: chest support to aid recovery following median sternotomy in female cardiac patients

KEY WORDS
- Bra
- Cardiac
- Healing
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Background: Female gender is an independent risk factor for surgical site infection (SSI) in coronary artery bypass graft (CABG) surgery. Previous studies demonstrated that SSI risk increases with breast size. In the UK, an affordable and suitable bra for cardiac surgery was not widely available in all sizes. **Aim:** To design a practical chest support for female cardiac patients, for in hospital and at home use. **Methods:** Using a quality improvement approach, the BHIS™ bra was developed. Continuous prospective SSI surveillance was performed by trained personnel. As a quasi-randomised design, retrospective propensity score matching was performed to adjust for non-random bra assignment. Variables of interest included bra type, cup size, operation type, operative urgency, cardiopulmonary bypass, body mass index, diabetic status, renal function and pre-operative stay. **Results:** 348 adult female patients with BHIS bra were matched with 348 adult female patients who wore a standard compression surgical bra and/or own bra. In the adjusted analysis, the BHIS bra had less SSI (Odds Ratio 0.56, 95% Confidence Interval [CI] 0.2324, 1.3557). **Conclusions:** The BHIS bra was designed specifically for the female cardiac surgical patients. Quality improvement data and retrospective case-study analysis suggests that BHIS bra is a useful adjunct to support wound healing. Further study via randomised control trial is needed.

Surgical site infection (SSI) following CABG surgery affects approximately 1 in 25 patients (Public Health England [PHE], 2016), though the true burden of SSI is suggested to be much higher. In a systematic review of post-discharge SSI, pooled estimates for CABG and Cardiac surgery proposed that the proportion of SSI occurring post-discharge in CABG surgery is 77% (CI 0.62; 0.93) and in general cardiac, it is 58% (CI 0.9, 0.66) (Woelber et al, 2016). SSI is a leading cause of readmission following surgery (World Health Organization [WHO], 2016). At our large cardiothoracic tertiary referral centre, an average of 391 days per annum are used to manage SSI readmissions (Rochon et al, 2016), which in turn translates to approximately £669,192 revenue lost per year (or capacity for 56 CABG cases). In addition to the pain and suffering, this complication places the patients at increased risk of sepsis. Mediastinitis is associated with a mortality rate of 33% (Margereson and Riley, 2003). SSI can impact on patient safety and experience, as well as affecting the Trust's reputation, and some cases may result in litigation.

Although females account for only a third of adult cardiac surgery patients (Society of Cardiothoracic Surgery, 2009), female gender is an independent predictor for SSI in CABG surgery using the BHIS score (Raja et al, 2015). In the PHE CABG and cardiac modules, female patients have a higher SSI risk (*Figure 1*). Over a five-year period, from January 2012 to December 2016, across the combined modules, the overall female SSI risk was 3.5% (401/11,300) and the overall risk for males was 2.7% (914/34,169). Interestingly, the non-adjusted risk ratio for gender in this dataset reaches significance in the CABG module ($p<0.001$, risk ratio 1.78 superficial SSI 95%CI 1.51–2.10; $p<0.001$ risk ratio 1.72 deep/organ 95%CI 1.42–2.10), but not in the Cardiac module ($p=1.0000$, risk ratio 0.99 and $p=0.7305$ risk ratio 0.90 respectively), noting both donor and

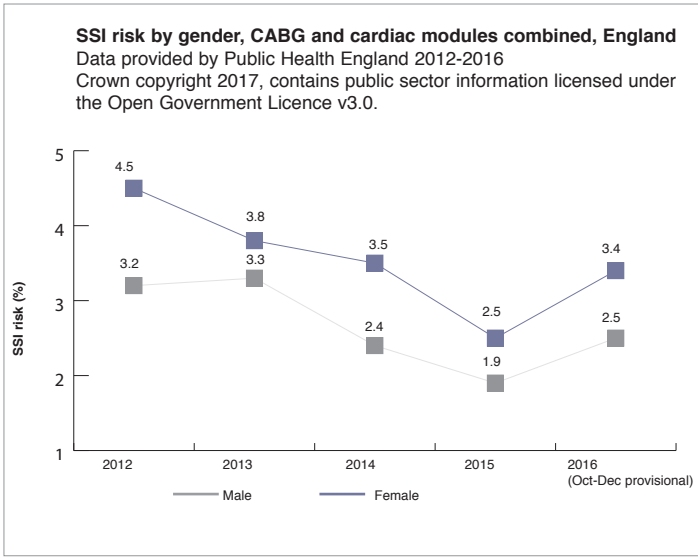

Figure 1. Female patients have a higher SSI risk

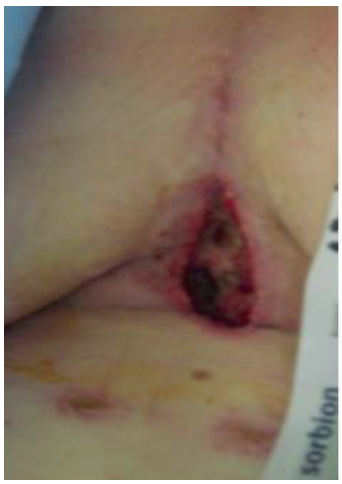

Figure 2. The distal end of the wound is vulnerable due to medial-lateral pull from the breasts

sternal SSI are included in the CABG dataset and that comorbidities may vary between the groups.

For the healing by primary intention to take place, the approximated wound edges need to be held together until the wound has healed sufficiently (Alexander et al, 2004). The weight of the breasts can cause openings at wound margins, increasing the risk of bacterial ingress (Brocki et al, 2010). SSI presenting distally on a female sternotomy wound, tends to be classified as superficial incisional SSI, unlike SSI affecting the proximal wound. Infections at the upper or proximal area are more serious, because they are at a higher risk of sinus formation and/or mediastinitis. SSIs confined to the distal end of the wound, particularly on females with thicker subcutaneous layer, are also distinct from an upper wound infection in that they tend to heal more quickly since are not so many anatomical layers involved in the healing process *(Figure 2)*. However, in these cases, deep SSI may develop from the initial skin/wound breakdown of mechanical origin.

A seminal case control study by Copeland and colleagues (1994) demonstrated that medium (C cup) and large cup sizes (i.e. macromastia ≥D) are at increased risk. The authors had limited data available on cup sizes, which reduced the size of their study (21 patients and 27 controls). The work reported that females requiring a C cup bra have an SSI risk of 12.3 % and females with larger breasts had an SSI risk of 38.5% (Copeland et al, 1994). The breasts are made up of glandular, fatty and fibrous tissue and as they contain no muscle, they may shift /displace, relative to their size. Because of this, the median sternotomy (central chest) wound may be placed under inferolateral tension by the weight of the breasts. For example, the D cup (the average size in the UK), each breast weighs just under a kilo each (800 grams) and when the patient is in a supine position this weight will shift to the sides, placing the surgical wound under significant strain. For this reason, Brocki et al (2010) recommend that women ≥D cup wear a support bra for 6–8 weeks following the sternotomy.

With the age and weight, the supporting framework from Cooper's ligament stretches, causing the breasts to droop (ptosis) (Alexander et al, 2004), and with menopause the breast tissue becomes somewhat atrophied. For these reasons, the area under the bust can be underventilated and moist. Any skin folds (intertriginous areas) provide a warm environment for bacteria and fungi to thrive (Yosipovitch et al, 1993; Metin et al, 2015; Tüzün et at, 2015) and in sufficient numbers, may pose a threat to the unsealed acute wound. A difference in microbiology between the genders has been noted, with females having more SSI cardiac recorded with pseudomonas species than males (Langelotz et al, 2014).

Most UK cardiothoracic centres recommend females with median sternotomy to wear soft, non-underwired front fastening support wear for the weeks following cardiac surgery (Cardiac SSI Network, 2015). A front fastening bra is preferred to allow easy access and review of the wound and also to prevent the rub or twist of the band across the wound, as could happen back-fasten style. A bra reduces the pull on the new wound bed, reduces pain and discomfort during the initial recovery period (King et al, 2006) and stops the skin on skin contact. At our hospital site, a surgical bra is employed in preference to an external chest support because of differences in function, cost and patient compliance.

However, patients and carers regularly commented that a suitable bra was not always easy to find, and that this was adding stress to an already worrisome time. One patient said: *'It*

Box 1. Examples of staff and patient feedback

"The BHIS bra is easy to measure, fit and adjust.'"
Sister on Cardiothoracic Surgical Ward

"The introduction of the BHIS bra in Cardiac Theatres was met with enthusiasm as this provided a more dignified and simpler method of providing additional support in post-operative female patients. Gone are the days of using sticky tape to bind women's breasts together to aid skin healing."
Theatre practitioner

"At home, the BHIS bra was very comfortable, gave me a great sense of support, and felt lovely and smooth to touch on my skin."
Patient comment

"A very comfortable bra, which is fit for purpose."
Patient comment

would be most helpful to know about the front fastening bras long in advance... it was a bit of a rush [during] an anxious time just before op'. Some women were unable to find a suitable bra in their size and this issue also came up at theatre level. An audit of 200 female patient bra sizes was undertaken and a significant proportion (52%) needed a D cup or higher (5% required E–G cup). There were three key practice implications:

- The current supplier of bras placed in theatre (with removable straps and front fasten) did not have adequate range of sizes
- The compression style of bra did not accommodate weight gain for a significant proportion of our patients, and in some cases this led to pressure ulcers or skin breaks under the axilla (as reported on internal incident reporting system)
- Some patients could not find suitable bras and this was a source of worry/stress.

METHOD

The quality improvement project took place at one hospital site in the UK. The project was placed on the Trust's register and ethical approval was waived. Key stakeholders including experts in cardiac SSI surveillance, cardiothoracic theatres staff, cardiac surgeons, Fitness for Surgery pre-admission staff, discharge team and tissue viability reviewed prototypes and training approaches with specialists in medical garments (industry partner, CUI International).

Key priorities for the design were:

- Support at the outer cup: the aim was to reduce the tension on the new wound bed, without compromising ease of respiration (ie compression style which 'presses chest down' was avoided)
- Stretchable and breathable material: after cardiac surgery and cardiopulmonary bypass there is often dramatic fluid and electrolyte movement from the extravascular space to the extracellular space (Margereson and Riley, 2003)
- Front fasten with clips for wound review, and to allow the bottom of the bra to be left unfastened while the wound was healing

Box 2. BHIS Bra Recommendations for Patient Pathway (©2016. Royal Brompton and Harefield NHS Foundation Trust)

Update Preadmission Letters/Wound Care Information (as applicable): Highlight prior to admission that soft, non-underwired bras are required for the post-operative period (at least two to rotate for washing).

Pre-admission staff and surgical ward staff training on how to measure for correct size (ie. measure patient in own bra, in seated position): This reduces waste (bras are single patient use and cannot be returned to stock once used). The seated position increases upper abdomen area and ensures a fit which will accommodate early weight gain/reduced mobility in the early post-operative period. Perform a submammary assessment to ensure skin is intact or inform medic to treat presence of remote infection.

Place bra at theatre level (after transfer from theatre bed to transfer bed): The healing cascade begins immediately; and if not done so, the opportunity to place the bra may be missed for the initial day(s) (rolling patients should be avoided until they are stable). A suitable bra design will have removable shoulder straps and front fastening to accommodate this. The bra can be sent home for washing, and returned for re-use.

Support wear is suitable across the cup sizes, including smaller sizes (i.e. A, B cup). Rationale: cup size is based on the difference between bust and band size. It is not unusual women with higher abdominal girth to have a 'smaller' cup size (because bust and stomach have similar girth). Wearing a bra may also be more comfortable from a privacy/dignity perspective in hospital, when the wound bed is frequently reviewed — discuss with patient rather than relying solely on clinical judgement. Contraindicated in certain cases e.g. chemotherapy or radiotherapy patients or extremely fragile skin

Leave hook and eye open at distal end (4 hooks) while skin is still healing (4–5 weeks): The tissue at distal end of the wound is vulnerable due to body habitus and mechanical pressures. The support from the BHIS bra to the bust is sufficient without the bottom hooks fastened.
Check fit daily: Ask the patient if the fit is comfortable, as well as checking that two fingers can fit comfortably under band at front, under axilla and under shoulder straps. The cups should appropriately support the bust (not be too tight or loose). Significant fluid weight gain (ie >10kilo) will likely change the band size needed.

Place gauze under the bra band to prevent moisture accumulation (Hartsell, 2008) and keep the wound covered with a dressing to protect. Consider other adjuncts for patients at high risk of SSI (using for instance the BHIS score [Raja et al, 2015]), such as negative pressure therapy (WHO, 2016) and/or chlorhexidine containing wipes for under the bust area (if used, allow the skin to air dry before putting on clean bra. Do not use on wound).

At home use: A clean bra daily (remove for showering) morning and night for the first 6-8 weeks for light splint support (Brocki et al, 2010).

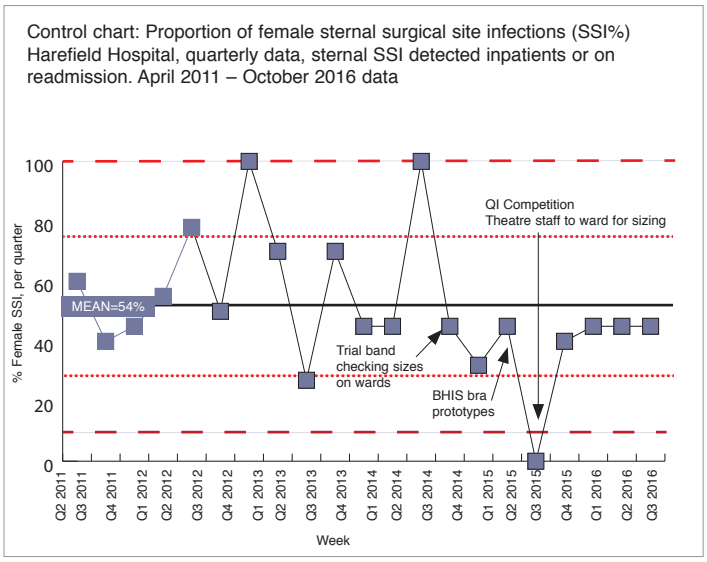

Figure 3. Control chart

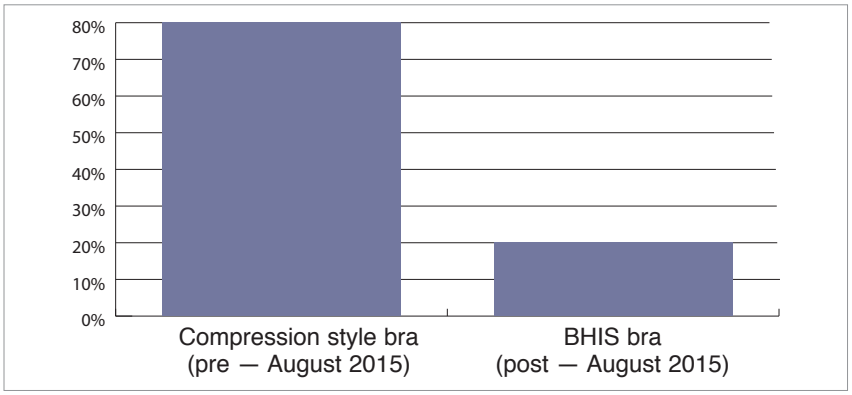

Figure 4. Proportion of female SSI of overall SSI(%) Sternal SSI (all types), detected on primary admission and re-admission Single hospital site: Cardiac surgery. April 2011—October 2016 data

- Cost and Size Range: as a product arising from and for the NHS and its patients, the price needed to be reasonable and a range of sizes available.

Across multiple Plan-Do-Study-Act cycles, the team trialled various prototypes including band and vest styles (with a mix of different features including Velcro, slides, zips etc). However, these did not sufficiently support the breasts from spreading on recline, therefore though accurate measurement would be required, the team agreed on an encapsulated (i.e. cup and band) style. Continuously and once a final design was approved, patient and staff feedback was sought using story consent forms (*Box 1*).

As part of the baseline data collected regarding staff awareness on the importance of support wear for female patients, it became apparent that a framework for practice across the patient journey was needed. The aim of the quality improvement project then became two-fold: to create a bra suitable for cardiac female patients with median sternotomy or submammary incisions and to determine best practice across the patient pathway in order to ensure patient comfort and protect wound healing (*Box 2*).

Continuous prospective SSI surveillance was undertaken by trained nurse specialists using the Public Health England 2013 protocol. Superficial sternal SSI were recorded up to 30 days, regardless of an implant, and deep incisional and organ-space SSI classification up to one year, if an implant was involved in the procedure, otherwise 30 days. Over the January 2012 — February 2017 period, the surveillance nurses recorded BHIS or non-BHIS support wear, as well as bra size. Generally, patient compliance with bra use (any type) was a high. The quality improvement project for the BHIS bra and training package demonstrated change in the process using control charts (*Figure 3*) and as a proportion of female SSI pre-and post-project implementation (*Figure 4*).

Following on from this, retrospective analysis of a prospectively collected cardiac surgery database (PATS; Dendrite Clinical Systems, Ltd, Oxford, UK). The data was collected and reported in accordance with the Society for Cardiothoracic Surgery in Great Britain & Ireland database criteria. Overall data on female patients was extracted from January 2012 to February 2017. From the 62 month period, 1236 female patients were identified with 41 sternal SSI detected on either primary admission or on readmission (sternal SSI rate 3.3%). 259 cases were excluded due to missing documentation of bra size. Patient eligibility was adult female with documented bra size with a cardiac and CABG OPCS code, as included in PHE SSI surveillance with SSI based on protocol definition (PHE, 2016). Data on bra size was available for 977 female patients were included, with 32 SSI recorded (sternal SSI risk 3.3%).

To reduce selection bias, data from the 977 study subjects was analysed and 696 cases were matched using BHIS bra or non-BHIS bra criteria.

Figure 5. BHIS bra (www.bhisbra.uk). Reproduced with kind permission from CUI International

281 observations were excluded by using 'nearest neighbour' matching. A propensity score (PS) was generated for each patient from a multivariable logistic regression model using the variables of interest: Bra type, cup size, Cardiac Operation, Operative Urgency, Bypass, Renal Impairment, Diabetic Status, Body Mass Index, Pre-Operative Length of Stay. Variables matched with nearest-neighbour 1-to-1 matching with a caliper width of 0.2 standard deviation of the logit of the PS. The quality of the match was assessed by comparing selected variables in propensity score balanced between the two groups. Propensity score matching analysis was performed using R (http://CRAN.Rproject.org/package=nonrandom) and MatchIt packages.

RESULTS

348 study subjects matched of BHIS and Non-BHIS support and was observationally balanced. The SSI risk was 2.3% (8/348) versus 4.0% (14/348) respectively; absolute risk reduction 1.7% (Odds Ratio 0.5613, 95% CI 0.2324 to 1.3557)

DISCUSSION

Findings from the retrospective matched case control study using propensity balancing to adjust for the non-random bra assignment suggests that the risk of SSI was 1.7 times greater in female patients using a standard bra compared to those with a BHIS bra. For this dataset, the 'cost avoided' £151,891 (6 cases at average cost of cardiac SSI of £27,751 ([2017 'constant price' i.e.compounded for inflation @2.5% from Rochon et al, 2016) [total £166,508] minus total BHIS bra cost for 348 units total £14,616 VAT inclusive).

The key driver of the quality improvement project was to create a bra available in a range of sizes, which was suitable and comfortable for women during the recovery period after cardiac surgery (Ford, 2017; McKew, 2017). An important design feature of the BHIS bra is its model cup support and gentle re-enforcement at the sides of the breasts (rather than to press the chest downwards) (*Figure 5*). This work builds on work previously published for the Brompton Harefield Infection Score (BHIS), wherein multivariate regression analysis was performed to estimate the independent effect of each of the repressors on the dependent variable (Raja et al, 2015). A limitation of the analysis 281 observations were excluded by using 'nearest neighbour' matching. Based our experience from the QI project, further studies are warranted. Any influence on SSI rates, either positive or negative, should be interpreted with caution because the healing process (respond, repair and remodel) can be influenced by a range of host and external factors. In addition to wound protection against mechanical forces, exacting surgical technique and robust infection prevention practices are essential in reducing SSI risk (Rochon, 2012).

Many of the recommendations from the BHIS training package are broadly applicable to support wear used across the patient journey. Poorly fitting bras may cause more damage than good. The distal end of the wound on female patients may be particularly vulnerable due a variety of reasons (*Figure 2*), for instance this area may have a deeper subcutaneous layer (thus requiring more suture material, or 'foreign body'), inframammary folds, it is point of diathermy exit (heat used during cardiac surgery) and in some cases the tissue is friable – if the area is placed under pressure from a too tight bra band it can cause the wound to break down and open to microorganisms in the areas adjacent to the wound.

Following the development of a successful BHIS training package, the BHIS bra is established for routine use at our Trust, including in theatres and at ward level, following a successful evaluation

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period. We agree strongly with Hjorth's point that in order to be useful and avoid potential complications, chest support must be comfortable and acceptable to the patient (Hjorth, 2014). Our QI work suggests that the BHIS bra satisfies these criteria, but similar to T.E.D.™ Anti-Embolism Stockings stockings, correct management is important and should involve patient education (Peters 1998, cited in Margereson and Riley, 2003).

CONCLUSIONS

PHE data demonstrates females have a higher SSI risk than male patients in general cardiac and CABG modules; in the latter module this difference is statistically significant in non-adjusted analysis. Although gender is a non-modifiable risk factor, simple strategies such as quality post-operative bra managed correctly, will aid the healing process if managed correctly. Correct fit is essential for the BHIS bra (or any bra placed with a new surgical wound), therefore accompanying recommendations are offered. Our quality improvement project is the largest that we are aware of in the UK using PHE's standard SSI surveillance methodology and extensive data on cup size. We attempted to adjust for bias and make the two groups more similar by matching on potential confounders, but further studies are needed. WUK

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