Variation in the perioperative care of women undergoing abdominal-based microvascular breast reconstruction in the United Kingdom (The optiFLAPP Study)

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Contributor statement

MDG and AM conceived the project; MDG and RMK formed the steering groups and were involved in every aspect of protocol design and delivery of the project; The optiFLAPP Steering Group developed the surveys, tested surveys and advised on delivery of the project; RMK performed the data analysis; RMK and MDG drafted the manuscript, all members of the optiFLAPP Steering Group revised the manuscript and act as guarantors. Members of the Undergraduate Working Group identified units,

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Abstract

Introduction

Abdominal-based microvascular breast reconstruction constitutes approximately one fifth of reconstructions following mastectomy for breast cancer. Enhanced recovery after surgery (ERAS) protocols have been implemented to improve patient care. The aim of this project was to identify variation in the perioperative care of women undergoing microvascular breast reconstruction to inform development of an ERAS protocol.

Methods

Surveys were developed for plastic surgeons, anaesthetists and the lead clinician for breast reconstruction at each unit. These assessed most aspects of perioperative care. A team of medical student collaborators was identified. This team created a list of surgeons and anaesthetists in the United Kingdom by unit. REDCap was used to record their responses.

Results

Nineteen (19/39, 49%) lead clinicians, 83 (83/134, 62%) plastic surgeons and 71 (71/100, 71%) anaesthetists from units across the UK completed the surveys. Marked variation was identified in the clinician responses when compared with the national and international guidance. This variation covered many aspects of patient care including antibiotic and fluid prescribing, surgical technique, postoperative care and recording of patient outcomes.

Conclusions

The optiFLAPP national practice survey has demonstrated variation in the perioperative care of women undergoing abdominal-based microvascular breast reconstruction. We propose a large prospective audit to assess current protocols and support development of randomised controlled trials.

Keywords: breast reconstruction, microsurgery, perioperative, deep inferior epigastric perforator flap

Introduction

In the United Kingdom (UK), abdominal-based free tissue transfer is the most common form of microvascular breast reconstruction used following mastectomy (1). Many of the technical challenges for flap survival have been addressed such that reported flap failure rates are below one percent (2). Increasingly the focus has turned to refining the patient pathway to improve quality of care and provide a cost-effective service.

Enhanced Recovery after Surgery (ERAS) protocols are multimodal perioperative care pathways that 'fast track' patient recovery by reducing unintended variation in clinical practice. In 2012, a protocol for microvascular breast reconstruction was included in national guidance published in the UK (3). A subsequent study highlighted variation in some aspects of perioperative care in this patient group (4). More recently, ERAS protocols were successfully implemented at single centres in the USA (5,6). In 2017, the ERAS Society published a breast reconstruction-specific protocol (7). The main limitation of the protocols is that many of the recommendations rely on expert opinion owing to a lack of high quality evidence. In addition, the guidance is often general rather than specific, which results in uncertainty. This provides space for variation in clinical practice. To date, none of the ERAS protocols have been correlated with validated patient-centred or patient reported outcomes.

Clinical variation presents a serious challenge to delivering effective healthcare. In the UK, the National Health Service (NHS) is using the "Get It Right First Time" (GIRFT) initiative to improve patient care and reduce costs by identifying and addressing clinical variation. The pilot study investigated delivery of orthopaedic surgery in the UK. It identified wide variations in the quality of treatment and outcomes achieved by hospitals across the country (8). For example, surgical site infection rates were 0.2% at the best performing hospital and 5% at the worse, a 20-fold difference.

The optiFLAPP (optimising FLuid And the Peri-operative Pathway in free flap surgery) study ultimately aims to develop an evidence-based ERAS protocol for use in abdominal based microsurgical breast reconstruction. As a first step, this article reports national practice surveys used to identify clinical

variation with respect to all aspects of the perioperative care provided to women undergoing surgery in the UK. This will inform the development of a prospective audit to further evaluate current practice.

Methods

Three distinct surveys were developed by a collaborative group of plastic surgeons and anaesthetists with an interest in microsurgical breast reconstruction, to evaluate current practice at each UK hospital undertaking such procedures (Files, Supplementary Digital Content 1, 2, 3 REDCap survey data dictionaries). The lead plastic surgeon for the breast reconstruction service for each unit completed the 'lead clinician' survey. It examined current service provision and local compliance with existing national protocols and guidelines. The 'surgeon' and 'anaesthetist' surveys given to individual consultants focused on key aspects of perioperative care including surgical technique, prescription of fluid, analgesia, antibiotics, venous thromboembolism prophylaxis, flap monitoring and clinician and patient-reported assessment of outcomes.

The study used an innovative methodological approach, with the dual aims of improving participation and establishing a national collaborative research network as a basis for future research and trials in plastic and reconstructive surgery. A medical student working group was established and took the lead in recruitment and data collection, with guidance from the steering group. The group first identified every UK NHS hospital providing microsurgical breast reconstruction, using a number of distinct sources to ensure completeness. They then recruited local medical student collaborators through advertisements placed with medical school surgical societies, national societies and relevant plastic surgery websites in the UK.

Medical students piloted the surveys at two sites, the Royal Marsden Hospital, London and Norfolk and Norwich Hospital, Norfolk. Respondents were asked to complete the surveys and provide feedback on

both the conduct of the medical student and the questionnaire content and structure. The surveys were amended based on the feedback to aid interpretability and ease of completion.

Medical student collaborators were provided with focused training on the study aims, how to communicate with and engage clinicians, and how to collect data using the survey tool. They were directed to compile a 'denominator' list of eligible clinicians from their hospital before being given the survey links. They approached each of the consultant surgeons and anaesthetists in person, providing them with electronic means with which to complete the survey (e.g. tablet, phone or laptop device).

Study data were collected and managed using REDCap electronic data capture tools hosted at the Kennedy Institute of Rheumatology (9). REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

Results

Collaborators collected survey data between June and December 2016. Nineteen (19/39, 49%) lead clinicians, 82 (82/134, 61%) plastic surgeons and 71 (71/100, 71%) anaesthetists from units across the UK completed the surveys (Supplementary Table 1). One of the largest units declined to take part in the project. The median estimated number of unilateral deep inferior epigastric perforator flaps performed in 2015 by a unit was 60 (IQR 20-79), and 16 (IQR 3-20) for bilateral reconstructions. Summaries of each of the surveys are in Supplementary Tables 2,3,4.

Preoperative care

In addition to their clinic appointment, patients most commonly received paper based information (89%) and the opportunity to meet with a breast care nurse (74%). There was minimal use of the Internet or App based information provision. Thirty-two percent of units reported providing detailed information on what a patient should expect on each postoperative day. Patients were usually seen in a nurse-led pre-assessment clinic (84%) rather than anaesthetist led clinic (11%). Most surgeons (58%) preferred to stop tamoxifen before surgery for a median of 3 weeks before and 2 weeks after surgery. Preoperative imaging was requested by 92% surgeons (CTA 67%, MRA 17%, duplex ultrasound 6%). However, surgeons felt they always used the best perforator on the scan only 22% of the time with 69% reporting using the best perforator 'most of the time'.

Patients were admitted either on the day before surgery (42%), the morning of surgery (37%), or seen on the day before and sent home overnight (16%). Mean predicted postoperative length of stay was five days.

On the day of surgery, 30% of surgeons always warmed patients preoperatively with a forced air blanket. Most anaesthetists (70%) reported not prescribing pre-emptive analgesia. 41% of surgeons and 31% of anaesthetists reported a formal perioperative fluid protocol. Most surgeons (93%) and almost all anaesthetists (94%) did not prescribe intravenous fluids pre-operatively. Most surgeons gave

general encouragement to drink water (40%). Only 13% surgeons and 23% anaesthetists gave a specific oral fluid prescription. For preoperative venous thromboembolism protection, surgeons reported using low molecular-weight heparin (61%), thromboembolic deterrent stockings (45%), and intermittent pneumatic compression devices (16%).

Intraoperative surgical technique

Ninety-three percent of surgeons preferred the internal mammary vessels as recipients rather than the thoracodorsal axis (7%). To access the internal mammary vessels, 52% always removed costal cartilage and 27% sometimes removed costal cartilage. Most surgeons always coupled the vein (67%) but a sizeable minority reported hand sewing (18%). When performing the anastomosis, the preferred irrigation solution was heparinized saline (87%) but topical vasodilators such as verapamil (29%) and papaverine (22%) were also used. When closing the abdomen, techniques to reduce the dead space were rarely used. Two drains were most commonly placed and there was a large range of wound closure techniques (Table 1). There was equipoise on use of mesh for rectus sheath closure, nylon suture for rectus fascia, PDS suture for Scarpa's fascia, and monocryl suture for deep dermal and subcuticular closure. Most surgeons do not apply an abdominal binder (57%). A majority of both surgeons (67%) and anaesthetists (69%) reported placing an abdominal peripheral nerve block (Supplementary tables 3 and 4).

Intraoperative drug administration and hemodynamic optimization

Anaesthetists reported no consensus on the type of anaesthesia used (volatile 37%; total intravenous 39%, combination 24%). Intraoperative haemodynamic assessment showed a range of views on different modalities. Total volume of fluid given was deemed important but central venous pressure was universally deemed not important (Supplementary table 4). Anaesthetists preferred Hartmann's solution and reported 2850 mL (min 1000 mL, max 8000 mL, stdev 1024 mL) as the mean volume of

intravenous fluid prescribed during a standard case. A majority of surgeons felt vasopressors were never warranted (66%), in contrast to 84% of anaesthetists who reported using them some or all of the time. The most popular agents were metaraminol (61%) and ephedrine (38%).

Most patients had a group and save performed (75%), rather than cross match (12%) or neither (7%). Routine measurement of intraoperative blood loss was split between always (42%) and never (36%). A haemoglobin level between 60 g/L and 80 g/L was the trigger for transfusion.

Postoperative care

The preferred postoperative environment was ward-based care in a designated 'flap' bay or room with an increased nursing ratio. This environment was usually temperature controlled (90%). In addition, the surgical preference was to have direct warming of both flap and patient with a forced air warmer (66%) rather than the flap alone (5%). A majority of surgeons preferred to discontinue antibiotics postoperatively (53%) but the rest chose to continue them in some form. VTE prophylaxis continued in the form of LMWH and TEDS. VTE prophylaxis was usually stopped on discharge (44%) but 29% surgeons provide prolonged prophylaxis beyond discharge. Flap monitoring used clinical observation with pencil Doppler as the preferred adjunct. The frequency of flap monitoring decreased with time (Figure 1).

The majority of surgeons placed two abdominal drains and removed them once the output was below a defined volume over 24 hours. A third of surgeons kept a patient in hospital until their drains were removed.

Formal post-operative quality of life surveys were used by 30% of surgeons. Of these, the most common surveys were Breast-Q (17%) and the NHS patient satisfaction survey (30%).

Postoperative intravenous fluid management

The majority of units (60%) did not have a formal protocol for postoperative fluid management. Non-invasive blood pressure monitoring and urine output were used to guide fluid prescribing. The main choice of fluids was Hartmann's solution (80%). Intravenous fluids were stopped on the morning after surgery by 36% but 54% continued IV fluids beyond this point. Surgeons were divided as to whether a urine output of greater than 2 mL/kg/hour was of concern.

Postoperative analgesia

Lead clinicians reported that only 31% of units always provided a pain team review for their patients but it was available in a further 42% as required. 57% of surgeons and 53% of anaesthetists preferred use of local or regional blocks. Of these, rectus sheath block was the most popular (33%) followed by the transversus abdominis plane (TAP) block (21%). Anaesthetist reported choice of postoperative analgesia (Table 2) included paracetamol (97% regular, 0% PRN), non-steroidal anti-inflammatory drugs (NSAIDS) (49% regular, 10% PRN), oral morphine (23% regular, 36% PRN), compound analgesics (7% regular, 10% PRN), and patient controlled analgesia (63%).

Discussion

This study identified marked variation in the clinician-reported delivery of perioperative care for women undergoing abdominal-based microvascular breast reconstruction. Some aspects of care differed significantly from the UK oncoplastic breast reconstruction guidelines for best practice (3), the recent ERAS consensus guidelines (7) and a recent systematic review (10) (Table 3).

There was variation reported amongst clinicians within units as well as between units. This was difficult to statistically analyse but there were units in which responses from clinicians were almost entirely the same and others where they varied widely. The reported clinical variation is likely to impact on quality of care, cost effectiveness and patient outcomes. However, for many of the elements it remains unclear

what constitutes best practice, owing to the lack of high quality evidence. For instance, the ERAS consensus guidelines recommended TIVA, owing to less nausea and vomiting, yet a recent evidence-based guideline for microsurgical free tissue transfer, recommended volatile anaesthesia (10). The surgical responses for intravenous fluid prescribing and the use of vasopressors reflected an historical view that plenty of intravenous fluid is required to maintain a 'hyperdynamic' circulation and that vasopressors should be avoided for fear of compromising the flap blood supply. Current best evidence suggests excessive intravenous fluid is detrimental and that vasopressor use does not lead to increased flap-related complications (11-13).

Length of stay is often used as an outcome measure. In some ways it reflects the speed of inpatient recovery and availability of post-discharge care and support systems. Along with staffing and operating time, it represents one of the main upfront costs of the procedure. Short hospital stays are preferred by patients, may reduce hospital acquired complications (e.g. infections and thromboses) and save the health service money. The median reported length of stay in this study was five days. This is at least two days longer than the published ERAS protocols, which may themselves be unrealistic. The staffing costs associated with the various protocols will vary. Patients with central lines, PCA analgesia, and requirement for frequent flap monitoring will consume more nursing time than those without. The direct procedure consumable costs are influenced by anaesthetist and surgical choices. For instance, the cheapest abdominal closure described entailed no use of mesh and simple suture-based closure of the rectus, Scarpa's fascia and skin, without the use of a dressing. The most expensive included routine use of mesh, multiple barbed sutures, and a wound dressing device. There is little evidence to support these different closure techniques or indeed the use of dressings specifically (14). There is an increased risk of abdominal wall hernia following abdominal flap breast reconstruction (15), and, the use of quilting sutures without drains results in shorter hospital stays and fewer seromata (16).

Collection of patient centred and patient reported outcome measures (PROMs) has become central to assessing the quality of patient care. The ABS / BAPRAS guidelines recommend the routine collection of PROMs. It was striking that only 17% of surgeons reported collecting a validated PROM for breast

reconstruction. The future use of PROMs and patient centred outcomes will be crucial for assessing the success of the ERAS protocols. Currently the UK National Flap Registry is using validated PROMs scales from the Breast-Q to address this, but the scales used are limited to breast area appearance rather than the full set of five domains, and participation rates are extremely low (17).

The main limitation of this study was that, as a survey rather than prospective audit, there may have been a degree of reporting bias. However, there was no incentive for clinicians to misrepresent their own practices, and marked variation was identified. Data collection using a national network of medical student collaborators undoubtedly improved participation. However, in places their involvement had a negative impact, with clinicians reluctant to engage with them. There was a hiatus in data collection over the summer vacation period and it was more difficult to gain responses from hospitals that were geographically remote from a medical school.

We would like to highlight some themes identified in this study that mirror areas of variation identified by previous studies and which appear to have made little progress. These include low uptake of ERAS protocols, limited use of modern multimodal analgesic regimes (18) and abdominal closure with use of drains. Ideally randomized controlled trials should be undertaken within these domains, including of different ERAS protocols. The latter may be challenging but a prospective audit of the different approaches with the subsequent introduction of a unified protocol would be feasible. A prospective audit would provide real world data on current practice and overcome the various survey associated biases. Based on our findings and the recent literature we are developing a proposed protocol as the starting point for a consensus meeting of clinicians and further Patient and Public Involvement (PPI). Analgesic regimes and abdominal closure would probably be amenable to randomised controlled trials. For instance, there is enough cohort data to support a trial of abdominal closure with quilting and no drains versus normal practice and drains.

Conclusions

This study highlights marked variation in the perioperative care of women undergoing abdominal-based microvascular breast reconstruction in the UK. It is likely that other countries experience similar levels of variation. The same surveys are now being completed in The Netherlands for comparison. We have made the data dictionaries freely available to facilitate this. The optiFLAPP is an important first step in greater sharing of current practice to identify areas for further study. Greater patient and public involvement is needed to prioritise the research alongside developing a collaborative approach amongst clinicians to improve the evidence base.

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Figure 1 Plastic surgeon reported frequency of flap monitoring over first 48 hours following surgery

Table 1 Plastic surgeon reported preferences for closure of abdominal secondary defect

Table 2 Anaesthetist reported preferences for postoperative analgesia

Table 3 Comparison of optiFLAPP responses with ERAS Society protocol and ABS/BAPRAS guidance

Supplementary digital content

File, Supplemental Digital Content 1, which shows the lead clinician REDCap data dictionary

File, Supplemental Digital Content 2, which shows the plastic surgeon REDCap data dictionary

File, Supplemental Digital Content 3, which shows the anaesthetist REDCap data dictionary

File, Supplemental Digital Content 4, which shows response rates and hospital caseload (not alphabetical)

Table, Supplemental Digital Content 5, which shows lead clinician survey responses

Table, Supplemental Digital Content 6, which shows plastic surgeon survey responses

Table, Supplemental Digital Content 7, which shows anaesthetist survey responses

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