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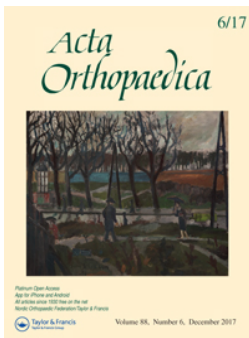
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Risk factors associated with intraoperative complications in primary shoulder arthroplasty

A study using the England, Wales and Northern Ireland National Joint Registry dataset

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Background and purpose — Increasing numbers of shoulder arthroplasty are performed internationally. The predictors of intraoperative complications when implanting primary shoulder replacements are unknown. We determined the incidence of intraoperative complications during primary shoulder arthroplasty using the National Joint Registry of England, Wales, Northern Ireland and the Isle of Man (NJR), and analyzed the associated risk factors for complications.

Patients and methods — NJR data on primary shoulder arthroplasty were scrutinized for intraoperative complications. 2 analyses were performed: the first examined the incidence and predictors of any recorded complication; the second examined the incidence and predictors for intraoperative fractures specifically. Analysis of risk factors was performed using multivariable binary logistic regression modeling.

Results — 12,559 primary shoulder arthroplasties were recorded, with an intraoperative complication rate of 2.5%, the majority being fractures (1.6% overall). The incidence of all complications was lower in men (RR vs. women = 0.63 (95% CI 0.47–0.84)). Patients undergoing surgery for avascular necrosis (RR = 2.3 (1.3–4.2)) or trauma sequelae (RR = 1.6 (1.2–2.7)) had a higher risk of complications compared with OA. Patients undergoing a stemmed hemiarthroplasty (RR = 1.8 (1.2–2.5)) and reverse shoulder arthroplasty (RR 1.6 (1.1–2.5)) had a higher risk of complications compared with total shoulder arthroplasty. The incidence of all complications was less in patients undergoing resurfacing arthroplasty (vs. total shoulder arthroplasty (RR 0.42 (0.24–0.73)) and when performing the superior approach (vs. deltopectoral (RR 0.56 (0.39–0.80))).

Interpretation — This is the first study to use a national data set to examine risk factors for intraoperative complications during all types of primary shoulder arthroplasty, and identifies several previously unrecognized risk factors, such as surgical approach. ■

The number of primary shoulder arthroplasties has been increasing worldwide over recent years, but reassuringly intraoperative surgical complications remain rare (Australian Orthopaedic Association 2015, National Joint Registry 2016, Steinmann and Cheung 2008, New Zealand Joint Registry 2014). However, when intraoperative complications do occur, they can increase operative time, change the type of implant used, increase blood loss, and alter postoperative physiotherapy regimes leading to slower rehabilitation (Boyd et al. 1992, Wirth and Rockwood 1994, Cuomo and Checroun 1998, Cameron and Iannotti 1999, Athwal et al. 2009).

Data on intraoperative complications are collected by a number of international shoulder joint registries including those in Norway and Australia, but are only regularly published by the National Joint Registry (NJR) of England, Wales and Northern Ireland (National Joint Registry 2016, Rasmussen et al. 2012).

The NJR is a rapidly expanding database, documenting over 2 million procedure-level records in the 2016 report (National Joint Registry 2016). Collection of data on shoulder arthroplasty started in 2012, and preliminary analysis suggests that over 95% of primary operations and over 90% of revision operations have been captured (National Joint Registry 2016). Data are entered immediately postoperatively by the surgeon in paper format, and locally uploaded electronically to the database. Individual surgeons and surgical departments can therefore be identified. Reporting is mandatory for hip and knee arthroplasty, but not for shoulders, though this is planned for the near future. The registry is financed by a levy placed on implants used for arthroplasty, and is otherwise independent of commercial interest.

Little is known about how often specific intraoperative complications occur, and the risk factors associated with each complication. This study uses the NJR database to investigate

the incidence of intraoperative complications during primary shoulder arthroplasty, and identifies risk factors for these complications.

Patients and methods

We accessed anonymized NJR data on all patients who had a primary shoulder arthroplasty between March 1, 2011 and March 31, 2015.

For all identified cases we obtained the data recorded on the NJR minimum dataset for primary shoulder arthroplasty. This included patient data (age, sex, ASA grade), surgical data (rotator cuff condition, indication for arthroplasty, type of arthroplasty, fixation type, surgical approach, lead surgeon grade) and details of any untoward intraoperative events.

The outcome of interest was intraoperative complications. Within the minimum dataset the surgeon is offered a number of discrete complication options from which he/she can choose. Listed complications include shaft penetration, fracture humerus, fracture glenoid, nerve injury, vascular injury, other or none. Due to the rarity of each individual complication, the complications were combined into 2 groups (1) all complications and (2) intraoperative fracture complications (shaft penetration, fracture humerus, fracture glenoid). Using these 2 groups we then performed 2 analyses; the first examined the incidence and predictors of any recorded complication; the second examined the incidence and predictors for only intraoperative fractures.

Statistics

Prior to statistical analysis continuous variables (age) were converted to categorical variables with category boundaries mirroring those used within standard NJR reporting. The distribution of responses for each variable was scrutinized and, where appropriate, responses were combined to ensure adequate numbers within each response group. For example, the number of operations where the lead surgeon was not a doctor of consultant grade (“UK trainee grade SpR/ST3-8”; “UK trainee grade F1-ST2”; “Non-training grade Specialty Doctor/Specialty and Associate Specialist”, or “Other”) was 1,268 (10%). Therefore to enable the grade of the lead surgeon to be treated as a covariate during subsequent analysis this group was combined to form a group of operations performed by a non-consultant grade lead surgeon. When recording the operation type the NJR minimum dataset includes the options “resurfacing arthroplasty of joint” and “resurfacing hemiarthroplasty of joint”. These 2 categories were combined for the analyses to produce a single “Resurfacing” group, as so few resurfacing total shoulder arthroplasty procedures were recorded (727, 4.2% of all the shoulder replacement procedures recorded).

Where multiple indications for primary shoulder arthroplasty were reported a decision was made to select a “pri-

Table 1. Operative indications for primary shoulder arthroplasty used in the analyses listed in order of hierarchy

| Order of preference | Indication for shoulder arthroplasty |
|---------------------|--------------------------------------|
| 1 | Acute trauma |
| 2 | Rotator cuff tear |
| 3 | Inflammatory arthritis |
| 4 | AVN/OA |
| 5 | Trauma sequelae |
| 6 | Other |

mary” indication for surgery for the purpose of analysis. This decision was made because creating groups of combined indications produced a large number (> 40) of groups containing small numbers of patients that would detract from the statistical analysis. Variations in recording the indication for arthroplasty on the NJR minimum dataset most likely represent different interpretations of the questionnaire and not true differences in the indication for surgery. For example, some surgeons reported the indication for arthroplasty as cuff tear arthropathy while other surgeons reported the indication as cuff tear arthropathy and osteoarthritis (OA). It is likely that both of these indications are the same. Table 1 gives the hierarchy of operative indication employed in cases where multiple indications were recorded.

Initial analysis involved calculating the unadjusted rates of all complications and fracture complications for each of the recorded variables. Binary logistic regression models were then constructed to examine the influence of the recorded predictor variables upon the 2 complication outcomes. First, univariate models were constructed to examine each predictor variable in isolation (unadjusted analysis). In order to allow a meaningful comparison between the variables it is important to account for potential confounding factors. Adjusted multivariable analyses were therefore performed using all available variables as simultaneous predictors for the outcomes under investigation.

Supplementary analyses were performed using chi-squared/Fisher’s exact test for comparisons of categorical variables, and ANOVA for continuous variables. For ANOVA testing a post-hoc analysis using the Bonferroni correction was carried out to minimise the risk of type one error. Within all analyses a p-value of < 0.05 was considered statistically significant. Only the p-values generated by the multivariable binary logistic analyses were used when considering the statistical significance of the results. 95% confidence intervals (CI) were calculated for relative risks. All analyses were performed using SPSS® (version 20.0, IBM Corp, Armonk, NY, USA).

Ethics, funding, and potential conflicts of interest

Ethical permission was approved by the NJR research commit-

tee. The authors received no financial support for the research, authorship, and/or publication of this article. No competing interests were declared.

Results

There were 13,078 primary shoulder arthroplasties recorded by the NJR since 2011. Complete data were available for 12,559 (96%) cases; the remaining 519 (4%) cases had not consented to storage of patient demographics and therefore these data were not available. The patients with complete data had a mean age of 72 years (range 20–100); 3,583 (29%) were male and 8,976 (71%) were female.

Of the 12,559 primary shoulder arthroplasties, 3,712 (30%) were total shoulder arthroplasties (TSA), 2,329 (19%) resurfacing arthroplasties, 4,590 (37%) reverse shoulder arthroplasty (RSA) and 1,928 (15%) stemmed hemiarthroplasties. The mean age of patients undergoing a conventional total shoulder replacement was 71 (22–94) years; for resurfacing arthroplasty this was 70 (20–96); for reverse shoulder arthroplasty 76 (23–100) and for stemmed hemiarthroplasty 70 (20–95). Patients undergoing a reverse shoulder arthroplasty were older than the other groups ($p < 0.001$).

Incidence of intraoperative complications

There were 315 (2.5%) intraoperative complications; 202 (occurring in 1.6% of all primary operations) of these were intraoperative fractures. The intraoperative fractures involved the humerus in 110 (0.9%) cases, the glenoid in 87 (0.7%) cases, with shaft penetration observed in 7 cases (0.1%). There were 7 (0.1%) vascular injuries, 3 (0.0%) nerve injuries, and 106 (0.8%) “Other” complications. Table 2 details the rates of complications dependent on patient and surgical demographics.

Risk factors for intraoperative complications

The incidence of all complications and intraoperative fracture was lower in men (RR vs. women = 0.63 (CI 0.47–0.84) and 0.51 (CI 0.35–0.75) respectively). The incidence of all complications and intraoperative fracture was lower in the age group 55–64.9 years (RR vs. ≥ 85 years = 0.55 (CI 0.31–0.97) and 0.43 (CI 0.21–0.86), respectively).

The indication for arthroplasty was associated with the incidence of complications. Patients undergoing surgery for avascular necrosis (AVN) (RR = 2.3 (CI 1.3–4.2)) or the sequelae of trauma (RR = 1.6 (CI 1.1–2.5)) had a higher incidence of all complications compared with patients undergoing surgery for OA. Patients undergoing surgery for acute trauma had a lower risk of all complications compared with patients undergoing surgery for OA (RR = 0.52 (CI 0.30–0.88)). Surgery for inflammatory arthritis or cuff tear arthropathy was not associated with an increased incidence of complications compared with the reference OA group.

Table 2. Rates of complications dependent on patient and surgical demographics. Values are count (percent)

| | Count | Complications | |
|-------------------------------|--------|---------------|-----------|
| | | All | Fracture |
| n | 12,559 | 315 (2.5) | 202 (1.6) |
| Age group | | | |
| < 55 | 765 | 18 (2.4) | 9 (1.2) |
| 55–64.9 | 1,667 | 25 (1.5) | 14 (0.8) |
| 65–74.9 | 4,649 | 123 (2.6) | 75 (1.6) |
| 75–84.9 | 4,617 | 120 (2.6) | 82 (1.8) |
| ≥ 85 | 861 | 29 (3.4) | 22 (2.6) |
| Sex | | | |
| Male | 3,583 | 62 (1.7) | 32 (0.9) |
| Female | 8,976 | 253 (2.8) | 170 (1.9) |
| ASA grade | | | |
| 1 | 969 | 19 (2.0) | 8 (0.8) |
| 2 | 8,200 | 193 (2.4) | 129 (1.6) |
| 3 | 3,274 | 98 (3.0) | 64 (2.0) |
| 4/5 | 116 | 5 (4.3) | 1 (0.9) |
| Indication for surgery | | | |
| Osteoarthritis | 6,831 | 134 (2.0) | 81 (1.2) |
| Rotator cuff tear | 2,914 | 97 (3.3) | 63 (2.2) |
| Inflammatory arthritis | 570 | 15 (2.6) | 11 (1.9) |
| Avascular necrosis | 290 | 15 (5.2) | 8 (2.8) |
| Acute trauma | 1,044 | 19 (1.8) | 15 (1.4) |
| Trauma sequelae | 690 | 31 (4.5) | 21 (3.0) |
| Other | 220 | 4 (1.8) | 3 (1.4) |
| Lead surgeon grade | | | |
| Consultant | 11,291 | 286 (2.5) | 186 (1.6) |
| Other | 1,268 | 29 (2.3) | 16 (1.3) |
| Operation type | | | |
| Total shoulder arthroplasty | 3,712 | 80 (2.2) | 52 (1.4) |
| Resurfacing arthroplasty | 2,329 | 17 (0.7) | 2 (0.1) |
| Reverse shoulder arthroplasty | 4,590 | 155 (3.4) | 103 (2.2) |
| Stemmed hemiarthroplasty | 1,928 | 63 (3.3) | 45 (2.3) |
| Fixation type | | | |
| Cemented | 1,915 | 55 (2.9) | 37 (1.9) |
| Uncemented | 6,537 | 142 (2.2) | 85 (1.3) |
| Hybrid | 4,107 | 118 (2.9) | 80 (1.9) |
| Surgical approach | | | |
| Deltopectoral | 9,884 | 262 (2.7) | 166 (1.7) |
| Superior | 2,161 | 39 (1.8) | 27 (1.2) |
| Deltoid split | 392 | 11 (2.8) | 7 (1.8) |
| Posterior | 76 | 2 (2.6) | 1 (1.3) |
| Deltoid detachment | 46 | 1 (2.2) | 1 (2.2) |
| Rotator cuff condition | | | |
| Normal | 5,252 | 100 (1.9) | 57 (1.1) |
| Attenuated | 3,079 | 80 (2.6) | 52 (1.7) |
| Torn | 3,831 | 130 (3.4) | 89 (2.3) |
| Repaired | 397 | 5 (1.3) | 4 (1.0) |

Patients undergoing a stemmed hemiarthroplasty (RR = 1.8 (CI 1.2–2.7)) had a higher incidence of all complications compared with patients undergoing a TSA. Patients undergoing an RSA had a higher incidence of all complications compared with patients undergoing a TSA (RR = 1.6 (CI 1.1–2.5)). The incidence of all complications and intraoperative fracture was reduced when patients were undergoing a resurfacing arthroplasty compared with patients undergoing a TSA (RR = 0.42 (CI 0.24–0.73) and 0.08 (CI 0.02–0.32) respectively). The approach used was also observed to influence the incidence of complications. Using the superior approach had a lower

incidence of all complications and intraoperative fracture (RR vs. deltopectoral = 0.56 (CI 0.39–0.80) and 0.63 (CI 0.41–0.97)).

In univariate unadjusted analyses, surgery in the presence of an attenuated or torn rotator cuff was associated with a higher incidence of all complications (RR 1.4 (CI 1.0–1.9) and 1.8 (CI 1.4–2.4) respectively) and intraoperative fracture (RR = 1.6 (CI 1.1–2.3) and 2.2 (CI 1.6–3.0), respectively) compared with surgery in the presence of an intact rotator cuff. However, when multivariable analyses were performed this association was no longer statistically significant. ASA grade, grade of lead surgeon, or implant fixation type were not associated with an increased incidence of all complications or fracture complications.

Tables 3 and 4 (see Supplementary data) show the relative risks for complications from the univariate and multivariable analyses of any intraoperative complication and intraoperative fractures.

Discussion

This study found an intraoperative complication rate of 2.5%, the most frequent of which was intraoperative fracture, with a risk of 1.6%. This was comparable with the findings of previously published literature, where overall intraoperative complication rates range from 1.9 to 6.2%, though the focus is often solely on intraoperative fractures, with a rate of 0.6–3% (Boyd et al. 1992, Wirth and Rockwood 1994, Wright and Cofield 1995, Cuomo and Checroun 1998, Cameron and Iannotti 1999, Worland et al. 1999, Bohsali et al. 2006, Chin et al. 2006, Groh et al. 2008, Steinmann and Cheung 2008, Athwal et al. 2009, Aldinger et al. 2010, Singh et al. 2012, Scarlat 2013, Waterman et al. 2015).

Although the rate of intraoperative complications during shoulder arthroplasty is low, we found a number of patient and surgical factors that increase the risk of these complications, including age over 85 years; female sex; and AVN or trauma sequelae as an indication for surgery. A lower risk for complication was found using a superior approach compared with a deltopectoral approach, and using a resurfacing implant compared with TSA, RSA, and a stemmed hemiarthroplasty.

Published rates of intraoperative complications vary substantially, often focusing upon a single complication, e.g. fracture, or a specific type of implant, e.g. RSA. To our knowledge, this is the first study to examine a variety of risk factors for several intraoperative complications during all types of primary shoulder arthroplasty using a large national dataset.

There is very little literature examining risk factors for intraoperative complications. 2 studies used univariate and multivariable analysis, and found that increasing age, female sex, and an underlying shoulder diagnosis of post-traumatic arthritis all increase the risks for any intraoperative complication

(including intraoperative fracture and neurological injury) (Singh et al. 2012, Waterman et al. 2015). These conclusions concur with our findings, making logical sense that risks are higher in patients with distorted anatomy, and those with poorer bone quality. Increasing age and female sex are known risk factors for osteoporosis, an important consideration when assessing risk of intraoperative fracture. However, the diagnosis of neither osteopenia nor osteoporosis is recorded on the NJR minimum dataset, so adjusted analysis to include osteoporosis to determine whether age and female sex remain increased risks is impossible.

To our knowledge, this is the first study to examine surgical approach as a risk factor for intraoperative complications, finding a superior approach to have a lower risk of intraoperative complication compared with the deltopectoral approach. A previously published French study indirectly noted a non-statistically significant decrease in complications with a superior approach compared with a deltopectoral approach (Mole and Favard 2007). One hypothesis for this finding could be that a specialist shoulder surgeon may be more likely to perform a superior approach, whereas “generalist” surgeons and trauma surgeons may perform a deltopectoral approach more frequently. By contrast, shoulder specialists performing a difficult primary shoulder arthroplasty for anatomical reasons not easily recorded on the NJR form, but nevertheless at higher risk of intraoperative complication, may be more likely to use a deltopectoral approach. Therefore, rather than the approach itself being to blame, the reason a specific approach is used may be the cause for the complication.

This reasoning may also explain why stemmed hemiarthroplasty produced the highest risk of intraoperative complications, which the dataset found to be mostly used in the trauma setting for acute fracture, possibly again by trauma surgeons or occasional shoulder surgeons. However, difficulty comes with any attempt to explain why a certain implant could lead to increased risk of intraoperative complication, as surgeons often choose a specific implant for a different patient group. Therefore, the risk of complication may well be related to the patient for whom an implant was chosen, rather than the implant itself. Resurfacing implants demonstrated the lowest risk of complications in this study, but are more frequently performed in younger patients, whereas reverse TSA is used in older patients, the highest risk population group.

Limitations

A benefit of registry data is that it allows large patient numbers to be analyzed. This can, however, generate a difference between statistical and clinical significance: a difference in absolute risk of 1% when using a certain surgical approach or implant may be highly statistically significant, but may not be enough clinically to alter the clinical practice of shoulder surgeons.

A limitation of registry studies is that the data are entirely surgeon-dependent, and collected immediately following the

operation. Reliance is placed on surgeons to admit complications, and some complications may not become apparent until after the dataset has been completed and submitted: for example, a nerve palsy, or undisplaced tuberosity fracture may not be obvious until well into the postoperative period, and thus not recorded on the NJR form. This may lead to an under-reporting of complications, which could explain why the risks of all intraoperative complications reported in this study are marginally lower than in most other studies published (Boyd et al. 1992, Wirth and Rockwood 1994, Wright and Cofield 1995, Cuomo and Checroun 1998, Cameron and Iannotti 1999, Worland et al. 1999, Bohsali et al. 2006, Chin et al. 2006, Groh et al. 2008, Steinmann and Cheung 2008, Athwal et al. 2009, Aldinger et al. 2010, Singh et al. 2012, Scarlat 2013, Waterman et al. 2015).

Another limitation is the possible residual confounding of data, a generic issue in registry studies. This is because the variables that can be included in the regression modeling, e.g. reasons for surgery, are limited by the data within the registry and the categories made available for selection on the minimum dataset for the operating surgeon to complete.

For example, the indications for surgery offered to surgeons include, amongst others, AVN and trauma sequelae: AVN is a known sequela of trauma, so crossover of diagnoses could potentially occur, which is a weakness of the NJR minimum dataset.

Following intraoperative fracture, “Other” complications (n = 106, 0.8% of all operations) occurred most frequently. Again, this is a designated variable in the NJR dataset collected by surgeons, and no further information is collected as to what this complication is, other than not being a fracture (glenoid, shaft penetration, or humerus), nerve or vascular injury. Further analysis of intraoperative complications would require more detail as to what specifically these “Other” complications entailed, as the definition of this category is in the hands of the surgeon completing the NJR dataset.

Supplementary data

Tables 3 and 4 are available as supplementary data in the online version of this article, <http://dx.doi.org/10.1080/17453674.2017.1362155>

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PC: original idea, data analysis, writing of manuscript, final editing; PH, PB: writing of manuscript, statistics, final editing; LK: writing of manuscript, data analysis; AR: original idea, writing of manuscript, final editing.

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