

# Open radical cystectomy: lessons from the British Association of Urological Surgeons (BAUS) registry

Marta Rossanese<sup>1</sup>, Enrica Subba<sup>1</sup>, Gianluca Giannarini<sup>2</sup>, Antonino Inferrera<sup>1</sup>, Vincenzo Ficarra<sup>1</sup>

<sup>1</sup>Department of Human and Paediatric Pathology “Gaetano Barresi”, Urologic Section, University of Messina, Messina, Italy; <sup>2</sup>Urology Unit, Academic Medical Centre “Santa Maria della Misericordia”, Udine, Italy

*Correspondence to:* Prof. Vincenzo Ficarra, MD, FEBU. Department of Human and Paediatric Pathology “Gaetano Barresi”, Urologic section, University of Messina, via Consolare Valeria 1, 98124 Messina, Italy. Email: vficarra@unime.it.

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In their recent paper published on the *BJU International*, Jefferies *et al.* performed a very interesting analysis of the British Association of Urological Surgeons (BAUS) radical cystectomy (RC) registry capturing approximately 83% of all open RC (ORC) cases performed in England in the period between 2014 and 2015 (1). This study provides a comprehensive focus on the current status of ORC in England, representing an important benchmark for any future comparison with emerging minimally invasive techniques and/or novel perioperative care pathways. It deserves special attention mainly because the BAUS cystectomy registry is a unique project worldwide with no other country mandating its surgeons to enter data at a national level with the ultimate goal to improve patient outcomes.

The BAUS registry included a total of 2,537 ORC during the study period. Most patients (73.6%) were male, and median age was 69 years. Indications reflected recommendations of international guidelines, with 46% of cases performed for muscle-invasive bladder cancer (MIBC), 13% for non-MIBC refractory to intravesical treatment and 10% for primary non-MIBC. Neoadjuvant chemotherapy was administered to 47.6% of patients with MIBC candidate to ORC. Interestingly, the median number of cystectomies performed per consultant was 13 (range, 1–158). The median number of procedures carried out per centre was 23 (range, 1–187). Interestingly, only few surgeons carried

out >30 procedures and only 19 centres performed >50 cases during the study period.

Excluding missing data, operative room (OR) time ranged between 3 and 5 hours in 52% of cases, was <3 hours in 11% of cases, and >5 hours in 36.5% of the procedures. OR time may be influenced by type of urinary diversion and extent of pelvic lymph node dissection (PLND). Indeed, 86% of patients received an ileal conduit, 5% an orthotopic neobladder and 2% of patients a continent cutaneous pouch. PLND was performed in 73.5% of patients included in the registry. PLND template included nodes from obturator fossa to common iliac bifurcation in 22.5% of cases, up to aortic bifurcation in 59% and up to the mesenteric artery in 18.5% of cases.

Examining the estimated blood loss (EBL), 41% of cases had an EBL <500 mL, 36% between 500 and 1,000 mL and 23% >1,000 mL. Excluding missing data, 25.3% of patients received blood transfusions. Positive surgical margins were detected in 198/1,983 (9.9%) cases.

Excluding missing data, overall complications were reported in 710 cases (32.8%). Major complications (grade 3–4) were reported in 10% of cases. Thirty-day mortality was reported in 40/2,537 (1.6%) cases. Moreover, 69/705 (9%) patients died <90 days after ORC. Unfortunately, for 1,763 (69%) patients this field was left blank in the registry.

Therefore, based on the above data, procedures

performed within 5 hours with an EBL between 500 and 1,000 mL not requiring blood transfusions and with a 30-day mortality rate <2% represent the current status of ORC with ileal conduit in England. Moreover, PLND with 11–20 retrieved nodes seem to be an acceptable quality metric (1).

This analysis prompts some considerations and comments. First of all, the BAUS has to be commended for this project aimed at improving the outcomes of patients undergoing RC. It is hoped that other scientific societies consider similar data collection at a time in which new surgical approaches become more and more popular. The success of this project is clearly due to the high percentage of procedures registered by consultant surgeons in a dedicated registry. Indeed, data coming from the Hospital Episode Statistics (HES) covering the same period as the BAUS registry recorded a total of 3,043 ORC procedures performed in England. Therefore, the BAUS registry represents the 83.4% of the ORC cases performed in England over the same time period. Notably, with the exception of 90-day mortality, the most critical information was correctly reported with only a low percentage of missing data.

A national analysis is a unique tool to measure the level of quality of surgery at different centres and to capture the outcomes across a large number of hospitals with different surgical volumes. The relevance of this analysis is to have a real picture of daily clinical practice beyond the best-of-the-best data usually published by referral centres on the most prestigious scientific journals. Moreover, as clearly stated by the Authors of the BAUS project, knowing the current standard of ORC is a fundamental step to properly address further comparisons with, above all, the main alternative to ORC, which is represented by robot-assisted radical cystectomy (RARC). Indeed, in 2013 data from National Cancer Database in US showed that 25% of RC were performed robotically (2). Urologists devoted attention to this minimally invasive approach and organised in 2015 in Pasadena the first consensus conference on RARC and urinary diversion with the aim to review the available literature and standardize the technical aspects (3,4).

The BAUS audit highlighted that data reported in literature should be interpreted considering the hospital and surgeon volume. RC with ileal conduit or orthotopic neobladder is a highly complex procedure with better perioperative outcomes observed in high-volume centres as well as in the hands of high-volume surgeons (5–7). Moreover, some recent population-based studies have demonstrated a survival advantages for patients treated in high-volume centres (6,8). Therefore, as recently supported

by the HES report in England, centralization of RC is strongly recommended to improve patient outcomes (9). However, very few and heterogeneous data are available that have examined the criteria to define the appropriate hospital and surgeon volumes. In 2003 in UK the improving outcomes guidance (IOG) recommended grouping of hospitals into networks with one centre carrying out almost 50 pelvic oncologic procedures with minimum 5 RCs per surgeon/year (10). In a systematic review of the literature published in 2008, high-volume centres were identified by a number of yearly cases >10–20 (11). In 2015, using a nationwide hospital discharge database, Leow *et al.* showed that cystectomies performed by surgeons with the highest volume ( $\geq 28$  annual cases) were associated with a lower odds of major complications compared with surgeons with the lowest volume (12). More recently, Waingankar *et al.* considered centres performing >30 cystectomies/year as high-volume (8). The BAUS audit showed that more than 10 years after the IOG recommendations, several centres in England performed <30 cystectomies per year with a median number of 23 (range, 1–187) cases (1). We believe that hospital volume should be an important variable for patients candidate to RC, and it should be declared as a potential quality indicator. In the last 5 years, our team performed 167 cystectomies at the University of Udine and 40 at the University of Messina with an estimated hospital volume of 42 cases/year in Udine and 40 cases/year in Messina. This high volume gave us the opportunity to standardize both surgical technique and postoperative care pathway in a multidisciplinary teamwork involving anaesthesiologists, nutritionists, rehabilitative physicians, internal physicians and specialised nurses (13). Looking at Pasadena recommendations on RARC, surgeons were defined experienced after 30 procedures and very experienced after 100 cases (4).

BAUS data showed that the ileal conduit is the most commonly performed urinary diversion in England. In details, 86% of patients received an ileal conduit and only 5% an orthotopic neobladder. The percentage of neobladder utilization in this registry seems to be lower than the one reported in a US population-based cohort analysed in 2013 (14). Data coming from the International Robotic Cystectomy Consortium showed that 80% of patients currently receive an intracorporeal ileal conduit and roughly 10% an intracorporeal ileal neobladder (15). Therefore, robotic surgeons are apparently utilising neobladder more than open surgeons in England. However, in our experience an orthotopic neobladder is performed

in 30–40% of cases receiving traditional ORC (13,16). Different patient-related factors can influence the choice of type of urinary diversion. However, the high percentage of incontinent urinary diversion reported in England is very likely correlated with the surgeon's preference. A critical analysis of counselling and decision-making processes should be performed to better understand if this metric is a reliable criterion of good quality in care. We believe that the high percentage of ileal conduit diversion reported in literature may be influenced by surgeon's preference and it cannot be regarded as a true indicator of quality. Obviously, ileal neobladder is more time-consuming and technically challenging than ileal conduit.

Another critical issue is represented by the percentage of patients receiving PLND. Indeed, in 26.5% of cases PLND was omitted. We believe that PLND should be considered always as part of RC in every patient with bladder cancer. Moreover, only 19% of patients receiving a PLND had a lymph node yield >20. These data are similar to those reported by a systematic review of the literature including data from RARC series with a median number of 19.3 retrieved nodes (17).

Looking at the intraoperative outcomes, the BAUS audit showed that the standard for ORC in England was to perform the procedure in an average OR time of 5 hours with an EBL of 500–1,000 mL without blood transfusions in 75% of cases. Unfortunately, perioperative data were not stratified according to hospital and/or surgeon volume. Therefore, the BAUS study failed to show whether centralization of RC to high-volume centres was associated with better perioperative outcomes. Comparing the current standard of ORC in England with data reported in international RARC series performed in the same time period, we can affirm that very expert robotic surgeons may reach better results in terms of EBL and transfusion rate, but with longer OR time. Additionally, major perioperative complications seem to be more frequent in RARC series ranging from 10% to 28% of cases, with a reintervention rate ranging from 9% to 33% of cases (18).

Although surgical margin status was not included in the summary of the standard of cystectomies in England, we believe that this variable represents a relevant oncologic indicator of quality. Excluding patients with missing data, about 10% of patients undergoing ORC between 2014–2015 in England had positive surgical margins. This percentage seems to be higher in comparison with previous and contemporary ORC series (19). Similarly, in recent RARC series median rate of positive surgical margins was

5.6% with a range between 0 and 25% (17). This parameter could be very important when comparing outcomes of ORC with those of RARC. Again, we believe that surgeon volume may play a pivotal role also with regard to this oncologic parameter. Unfortunately, the BAUS analysis does not report on other oncologic data, such as early local or distant recurrences.

Indeed, a recent RCT comparing ORC and RARC documented lower local and regional recurrence rate in ORC patients with a non-statistically significant trend in favour of ORC in for distant recurrences (20). In details, 3 cases of soft tissue disease with direct rectosigmoid invasion and 5 cases of abdominal wall invasion with synchronous bowel implants were reported in the RARC arm.

The IOG recommendations to group the pelvic oncological procedures in high-volume centres performing more than 50 procedures/year improved 30- and 90-day mortality from 2.2% to 1.3% and from 5.8% to 2.6%, respectively, between 2003 and 2013 (21). The BAUS registry confirmed in the next 2 years a 30-day mortality rate of 1.6%. However, the 3-mo mortality rate resulted 2.7% including missing data and 9% excluding missing data. Obviously, the high percentage of missing data (69%) is a strong limitation of the BAUS study preventing any consideration about this important outcome. In our experience, the 3-mo mortality rate ranged between 2% and 3% of cases, with higher percentage in patients aged >80 years (13,16,22). These percentages seem to be similar to those reported in contemporary RARC series ranging from 1% to 3.5% 3-mo after RARC (18).

In conclusion, the BAUS study gives us an interesting picture of the current standard of ORC in England. Monitoring relevant parameters of surgically complex procedures is a virtuous initiative, which should be imitated by all other modern health systems with the aim to improve the quality of the surgical procedures. In the case of ORC in England, most perioperative outcomes are comparable with those reported in other surgical series, with the exception of the percentage of cases receiving an ileal conduit and 3-mo mortality rate. As pointed out by the authors, these data will be used as reference for comparison with all new techniques and modifications introduced in the next years. The main limitation remains the lack of data stratification according to hospital and surgeon volume.

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## Footnote

*Conflicts of Interest:* The authors have no conflicts of interest to declare.

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