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Response to “RE: Escalation of Care in Surgery: A Systematic Risk Assessment to Prevent Avoidable Harm in Hospitalized Patients”

Reply:

We would like to thank Dr Stevenson et al for taking the time to write their letter regarding our recently published study detailing a Healthcare Failure Mode and Effect Analysis of the escalation of care process in surgery.¹ They concisely identify both strengths and limitations of the study. In the letter, Stevenson et al comment on the number of hours spent observing staff, the role of patients in the escalation of care process, the nature of controlled and uncontrolled failures in the pathway, and the overall recommendations of the study.

Regarding the number of hours that were spent observing staff, Dr Stevenson et al state that this was limited and may have led to an underestimation of process failures. However, this interpretation of the methodology is flawed. As escalation of care is an interprofessional process, it involves patients, doctors, nurses, and multiple other health professionals. This means that although the number of individual hours spent observing each staff member may seem small, during these observation periods, the observers were exposed to a plethora of hospital patients and staff. Therefore, the level of detail we were able to collect during these sessions was rich and comprehensive. Stevenson et al also query the clarification of the criteria used to identify a deteriorating patient. During the study design, we elected not to use strict criteria because all patients are different and there are multiple factors affecting the

decision to escalate care.² Two patients with the same physiological parameters may have very different outcomes depending on whether a delay in escalation of care occurs.³ Therefore, although these measurements are useful, a degree of intuition on the part of staff caring for patients will always contribute to the escalation of care decision.

Stevenson et al rightly comment on the role patients may play in alerting staff to a change in another patient's condition. This step formed part of the original flow diagram used in the study but was later removed after the participants rated it as nonhazardous. Similarly, the comments from Dr Stevenson et al regarding the distinction between controlled and uncontrolled failures are met with the same response. These were the views of the participants and not the authors. The combination of new technology (eg, an electronic vital signs chart) with human factors education is crucial if new innovations are to be successful. We agree that human factors are paramount to improving escalation of care and patient safety,⁴ in addition to the key role played by culture, which was identified in the original article and expanded upon in the accompanying editorial.⁵

Our study represents a fact-finding mission to establish the areas within the escalation of care process that have the greatest potential for successful intervention and the possible nature of these interventions. Human factors including education, process-driven care, and resource management are several of the many strategies that may be used. We hope that the study encourages both health care professionals and researchers to continue exploring and improving the escalation of care process to bring about the ultimate goal of improving care quality for patients.

Disclosure: Drs Johnston, Arora, and Darzi are associated with the National Institute for Health Research (NIHR) Imperial Patient Safety Translational Research Centre. The views expressed are those of the author(s). The authors declare no conflicts of interest.

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Robotic Nipple-sparing Mastectomy and Immediate Breast Reconstruction With Implant: First Report of Surgical Technique

To the Editor:

Technical innovations have made it feasible to conduct endoscopic nipple-sparing mastectomy (NSM), which has been reportedly well tolerated and associated with greater patient satisfaction.¹ However, the endoscopic technique (ET) has not had a wide diffusion and many centers have abandoned this technique because of technical challenges.^{2–4} In fact, the manual control of a 2-dimensional endoscopic in-line camera produces an inconsistent optical window around the curvature of the breast skin flap. Furthermore, the internal mobility results are limited and the dissection angles inadequate^{5,6} because rigid tips instruments are working through a single access.

The aim of the present study was to evaluate feasibility, safety, advantages and limitations of robotic surgery to perform NSM and immediate breast reconstruction (IBR) with implant. Our hypothesis is that robot technology could exceed the technical limits of ET. We describe the surgical technique of the first 3 operations carried out.

To exercise caution with regard to the oncological safety, we selected BRCA mutation carrier patients with a previous history of breast cancer surgery who had decided to receive a delayed contralateral risk-reducing NSM and IBR.

A 2.5-cm-long extra-mammary axillary incision was made so as to be hidden by the arm. The subcutaneous flap was dissected with electrocautery under direct vision in a 3 cm area. We then obtained a working space



FIGURE 1. Single-port axillary access before robot docking and instrument positioning.

for the introduction of the single port (Access Transformer OCTO, Seoul, Korea) connected to an insufflator to keep the pressure at 8 mm Hg (Figure 1) and commence the mastectomy. All the operations were carried out by the same surgeon at the console using a DaVinci S (Intuitive Surgical, Sunnyvale, CA) robotic platform. The robotic arms' elbows were opened as much as possible to avoid conflicts during dissection. The cavity was observed through a 30° 12-mm-diameter camera (Intuitive Surgical, Denzlingen, Germany). Dissection was carried out with a 5 mm monopolar cautery with spatula tip (Intuitive Surgical, Sunnyvale, CA) used on the right robotic arm. Traction and counter-traction, along with maintaining exposure and stretching out the tissue, was carried out with a 8 mm Maryland Bipolar Forceps (Intuitive Surgical, Sunnyvale, CA) fitted on the left robotic arm. The dissection started from the superficial flaps in all quadrants, then breast tissue was pulled up to create a sufficient posterior working space on the major pectoral fascia and completed dissection. The gland was then removed entirely en bloc through the 2.5 cm axillary skin incision using a "waving flag technique," moving the slippery and greased gland freely and gently back and forth or up and down (greater size of the gland was $8.5 \times 3.5 \times 2$ cm; areolar flap thickness ranged between 0.3 to 0.5 cm). In the reconstructive phase, as the gas pressure was not high enough to elevate the pectoralis major muscle, the monoport was removed and a long and narrow standard retractor was used to lift the muscle, although maintaining the same axillary access and the same robotic instruments. The submuscular pocket was prepared for adequate muscular distension. The drains and implant (Allergan Inc, Irvine, CA) were than inserted manually.

Surgical time was 7 hours for the first operation and 2 hours and 30 minutes for the last one. The first case was converted to an open technique near the end of the procedure

to reduce the time of surgery (20% of the gland dissected using traditional scissors). No variation of pathologic review of the breasts were registered. In the first patient we observed a biceps brachii temporary strength reduction, which resolved spontaneously. The last patient had a mild ecchymosis in the lower quadrants and a small blistering from internal electrocautery. All patients were discharged on the second postoperative day. After a mean follow-up of 8 months, no long-term complications were observed.

Although experience with NSM carried out by robotic-assisted technique is very limited and initial, we clearly noted 2 main advantages:

- (1) The use of carbon dioxide enables the reduction of bleeding, offering a better view of the proper surgical dissection plane. The tenfold image magnification, the 3-dimensional view, and the intense lighting increase the difference in contrast of colors of different structures, thus highlighting blood vessels, lymphatics, adipose lobules, the crests of Duret, Cooper's ligaments, the mammary gland itself, and the skin. Sharpness and clarity of the image, associated with a high precision of the instrument movement, stability due to tremor abolition and greater accuracy, permitted a better detachment of the gland by its suspensory ligaments. In addition, the robotic optical window allowed the intercostal perforators to be readily recognized and saved, which contribute significantly to the overall circulation of both the nipple-areola complex (NAC) and the mastectomy flaps.⁷ Furthermore, the robotic instruments have 7° of freedom of motion at the tips which allows negotiation around the curvature of the breast skin cupola. All these features have been reported as being a limitation of ET.^{7,8}
- (2) The minimal incision hidden in the axilla and the high respect for anatomical structures lead to high trophism and vitality of the NAC. In our opinion, this minimally invasive approach might reduce changes in the woman's body image, thereby increasing patient satisfaction.

On the other hand, we acknowledge 2 main limitations:

- (1) The setting of the surgical technique and the use of devices designed for other kinds of surgeries determines the duration of the operations. Certainly the learning curve seems rapid since the duration of the third operation was 3 times shorter than the first, coming very close to the standard open technique operating time.
- (2) Since this is the first report of robotic mastectomy, the bibliographic literature search did not yield any specific publications on cost analyses. Selber et al^{3,8,9} state that the marginal cost of using the robot only for breast reconstructive surgery (latissimus dorsi harvest) is the additional operating room time and the cost of the instruments. The sharp reduction of the operating time we observed during the first 3 operations might at least partially overcome the issue of operating room time. In addition to these costs we would add that the amortization costs of the robotic platform should be taken into consideration.

The encouraging preliminary results of the first operations endorse a prospective study aimed at evaluating patient satisfaction due to a more respectful mastectomy, not only as a risk-reducing surgery but also as a therapeutic procedure.

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Comparison of Surgical Resection and Radiofrequency Ablation for Hepatocellular Carcinoma: Take Care Not to Neglect Radiofrequency Technic and Device

To the Editor:

We read with great interest the study of Liu et al¹ comparing surgical resection (SR) and radiofrequency ablation (RFA) for single hepatocellular carcinoma (HCC) 2 cm or less. The authors assessed hazard ratio of RFA versus SR with multivariate cox regression and did not find a significant

benefit of SR as compared with RFA for overall survival. Survival curves carried out using Kaplan–Meier method and compared with log-rank test were not different ($P = 0.136$). However, considering the potential selection bias due to differences in each group baseline characteristics, the authors carried out a paired matching according to propensity score and found a better overall survival after SR ($P = 0.001$). They concluded that SR should be considered as first-line treatment for very early HCC.

After carefully reading this article, we think that several nondiscussed limitations could challenge the conclusion of the study:

1. It is not clear whether all patients were cirrhotics. The term used by the authors “chronic liver disease” suggested that non-cirrhotic patients were also included. The lower ALT and INR level, the higher platelet count and albumin level in SR group could also be explained by the presence of noncirrhotic patients in SR group. The mean Child-Pugh score did not differ between both groups and was very low (5.2) so it seems difficult to explain the previous cited differences only by a higher portal hypertension in the RFA group. To know if noncirrhotic patients were included is critical. Indeed Child-Pugh A cirrhotic patients had a lower expected overall survival and disease free survival after treatment even if their serum biochemistries baseline characteristics did not differ from noncirrhotic patients: established cirrhosis is an independent predictor of poor overall and recurrence-free survival.²
2. The propensity score building does not seem optimal. The role of propensity score is to limit initial selection bias of observational studies.³ Using propensity score needs to respect several conditions, the main one being that treatment assignment is independent of the potential outcomes conditional on the observed baseline covariates. This condition is also referred to as the “no unmeasured confounders” assumption: the assumption that all variables that affect treatment assignment and outcome have been measured. However, it seems that Liu et al chose to include only a few variables in the propensity score (age, sex, serum bilirubin and AFP level, platelet count, tumor volume, and performance status); it remains unclear whether albumin, INR and ALT level, HBsAg, and Child-Pugh score (CPS) were used to build propensity score. These variables could influence the patient’s outcome and were significantly (or almost for CPS and HBsAg) different between both groups, unfavorably for RFA group. Furthermore, if noncirrhotic patients were included in

the study, cirrhosis should be taken into account in propensity score. The confounding effect of variable not included in propensity score may still be present even if P -values of group’s comparison were no more significant after matching. Indeed, P -value higher than 0.05 given by the Mann-Whitney U test (used in this study) reflect that the distributions of the 2 populations have the same shape and not that paired matched patients had similar albumin or ALT level; that is why the confounding effect of these nonincluded variables is not avoided. Furthermore, these variables should also be included in cox regression.

3. The results evolution after propensity score matching is surprising. Indeed, baseline characteristics are mainly unfavorable to RFA group, which has the worst liver function reserve. However, after matching on propensity score, the 5-year overall survival after RFA decreased, from 76% to 66%, whereas the unfavorable initial selection bias should be corrected (as illustrated by the higher mean platelet count in RFA group after matching (134 G/L) than before matching (124 G/L). So, the outcome became worse when improving baseline characteristics? An explanation could be the higher tumor volume in RFA group after matching (2.4 cm³) than before matching (2 cm³), but as we discuss below, this explanation remains unsatisfying. Furthermore, the results after propensity score are at odds with multivariate cox regression result. It should be recalled that multivariate cox regression is also a way to take into account confounding factors, so it is unfortunate that the authors did not discuss these discordant results.
4. The authors explained the superiority of SR after matching by removing satellite nodule and microvascular invasion. They also wrote that their single-tip percutaneous RFA offered a necrotic area of 3 to 4 cm in diameter (page 7 line 12). So the margin after RFA for single tumor 2 cm or less should be closed to margin size reported for SR (mean 1.1 ± 1.1 cm). As well demonstrated by Sasaki et al⁴ satellite nodule beyond 5 mm are scarce for HCC 2 cm or less, so RFA with satisfying margin and SR should both be able to remove satellite nodule. This point is another major limitation.
5. The RFA device seems not optimal. First, the duration of inclusion is long and RFA devices have been improved because the beginning of the study (2002). Second, the 2 references given to validate the necrotic area up to 3 to 4 cm in diameter did not use the same RFA device. In this study, the