Surgical Endoscopy
https://doi.org/10.1007/s00464-021-08508-9

Efficiency in image-guided robotic and conventional camera steering: a prospective randomized controlled trial

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Received: 9 December 2020 / Accepted: 7 April 2021

Abstract

Background Robotic camera steering systems have been developed to facilitate endoscopic surgery. In this study, a randomized controlled trial was conducted to compare conventional human camera control with the AutoLap™ robotic camera holder in terms of efficiency and user experience when performing routine laparoscopic procedures. Novelty of this system relates to the steering method, which is image based.

Methods Patients undergoing an elective laparoscopic hemicolectomy, sigmoid resection, fundoplication and cholecystectomy between September 2016 and January 2018 were included. Stratified block randomization was used for group allocation. The primary aim of this study was to compare the efficiency of robotic and human camera control, measured with surgical team size and total operating time. Secondary outcome parameters were number of cleaning moments of the laparoscope and the post-study system usability questionnaire.

Results A total of 100 patients were randomized to have robotic (50) versus human (50) camera control. Baseline characteristics did not differ significantly between groups. In the robotic group, 49/50 (98%) of procedures were carried out without human camera control, reducing the surgical team size from four to three individuals. The median total operative time (60.0 versus 53.0 min, robotic vs. control) was not significantly different, $p = 0.122$. The questionnaire showed a positive user satisfaction and easy control of the robotic camera holder.

Conclusion Image-based robotic camera control can reduce surgical team size and does not result in significant difference in operative time compared to human camera control. Moreover, robotic image-guided camera control was associated with positive user experience.

Keywords Laparoscopic camera holder · Solo surgery · Active robotic camera steering · AutoLap™ system

The vast majority of all laparoscopic procedures are still performed by a standard team consisting of a surgeon, camera assistant, scrub nurse and circulating nurse. Camera control by a human assistant has a number of drawbacks, including personal interpretation on optimal field of view, tremor, unintended rotation and tissue contact. Robotic camera steering devices, controlled by the surgeon, could overcome these drawbacks.

Numerous robotic camera holders have been integrated into laparoscopic surgery since the introduction of the AESOP in 1994. Research demonstrated advantages including stable imaging, less instrument clashing, improved ergonomics and the ability to perform solo surgery [1–8]. However, acceptance and uptake has been limited. Current systems are controlled by voice, foot switch, joystick, eyeball tracking or head movements. These methods are effective in steering but lack intuitive control and tend to result in major disruption of the surgical flow and prolonged operating times [9].

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Recent developments in image recognition algorithms have created new possibilities for intuitive camera control [10]. It provides the opportunity for real time instrument tracking during surgery [11]. This technology is subsequently used to navigate the camera [12]. The AutoLap™ system (Medical Surgery Technologies ltd, Israel) was the first clinically used robotic camera holder to incorporate real time image-guided robotic camera control. Navigation of the camera with this feature is fast and simple: only one click on a finger joystick is needed to reposition the camera. We hypothesized that the use of image-guided robotic camera control might offer the desired intuitive camera control and has the potential to increase the uptake of robotic camera holders.

Safety, feasibility and ergonomic benefit of the AutoLap™ system have already been demonstrated in previous studies [8, 12]. We designed this randomized controlled trial to investigate whether image-guided robotic camera assistance can increase the efficiency of a variety of laparoscopic procedures in terms of surgical team size and operating time.

Methods

This prospective randomized controlled study (NCT02934542) was performed in the Meander Medical Center, Amersfoort, The Netherlands. The local medical ethics committee (Medical Research Ethics Committees United) and the board of directors of the hospital approved the study. Between September 2016 and January 2018, patients scheduled for elective laparoscopic right colectomy, laparoscopic sigmoid resection, laparoscopic fundoplication or laparoscopic cholecystectomy were screened for inclusion at the outpatient clinic. Inclusion criteria were: patients with the diagnosis of a cT1-3 adenocarcinoma localized in the caecum or ascending colon; cT1-3 adenocarcinoma in the sigmoid colon above the peritoneal deflection; sliding hiatal hernia (type 1) and paraesophageal hernia (type 2); or symptomatic cholecystolithiasis. Exclusion criteria were age < 18 years, pregnancy, body-mass index (BMI) of more than 35 kg/m^2 and patients with absolute contraindications for laparoscopic surgery. Laparoscopic procedures converted to open surgery were excluded from the study and replaced. A patient was withdrawn from the study and replaced if the robotic system was not available at the time of surgery due to logistical reasons.

After providing written informed consent, patients were randomized to receive either laparoscopic resection as per standard practice or robotic camera assisted laparoscopic resection. All patient data and study parameters were recorded on a secured database and randomized using stratified block randomization (Castor EDC, The Netherlands). In advance of this study, a sample size calculation was executed. A total of 100 patients were included to detect a difference of 25% in personnel resources between the two groups (one surgical team member). The assumption was made that at least 80% of the procedures in the robotic group could be performed with no more than three surgical team members. A power of 80% and a significance level of 0.05 were used.

The primary outcome was the comparison of the surgical team size and the total operating time in minutes. Surgical team size was defined as the number of individuals participating in the surgery. This included the sterile team members (surgeon, camera assistant, scrub nurse) and non-sterile team members (circulating nurse). Individuals from the anesthesiology department were not included. Total operating time was defined as the as the skin-to-skin time, which is the time between the first incision and last skin closure. This included the setup time of the robotic system in the AutoLap group. Setup, draping and positioning of the system was performed by the circulating nurse.The time was recorded and documented by the study group. In addition, the number of cleaning moments of the laparoscope were documented. A cleaning moment of the laparoscope was defined as an out of patient cleaning process of the laparoscope.

Post-surgery, the surgeon's satisfaction and performance of the image-guided robotic camera steering was evaluated with the Post-Study system Usability Questionnaire (PSSUQ) version 3 [13, 14]. This validated questionnaire consists of 16 items and follows a 7-point Likert scale. It ranges from 1 (strongly agree) to 7 (strongly disagree), and therefore the lower the score, the better the performance and satisfaction. The overall result is calculated by averaging the total scores. The questionnaire can be broken down into three sub scores; the system usefulness score, the information quality score and the interface quality score.

Five experienced surgeons, three consultants and two specialty registrars, participated in this study. All surgeons were familiar with the functionality of the robotic camera holder. The standard surgical team in the conventional laparoscopic study group consisted of four individuals; a surgeon, a camera assistant, a scrub nurse and a circulating nurse. Camera assistance was performed by medical personnel with varying experience, ranging from interns to senior residents and scrub nurses. The robotic camera holder replaced the camera assistant in the robotic group, reducing the surgical team size to three members.

The AutoLap™ system consists of a robotic motion assembly unit and a processing unit. The processing unit includes the system's electronics and software algorithm that enables instrument tracking. The robotic motion assembly unit holds the laparoscope and is mounted on the operating table rail. This negates the need for calibration if the table position is altered. The robotic motion assembly unit is covered by a sterile drape at the start of the procedure. The image-guided software is able to recognize any laparoscopic instrument and does not need special markings on the instruments. Control over the image-guiding software is activated by pressing on a sterile wireless joystick, attached to the surgeon's finger or instrument. A virtual marker appears on the screen, marking the tip of the instrument and subsequently the instrument is moved to the desired surgical field. Releasing the button on the joystick automatically readjusts the camera to the desired working space. Additionally, the system has two other modes of operation that can be selected: a manual operation mode and the joystick mode. Surgeons can alter between these steering modes depending on their preference. A more detailed description of the system has been published previously [12].

Statistical analysis

The data were analyzed using SPSS (IBM SPSS Statistics for Windows, Version 24.0, Armonk, NY). Outliers and distribution of the data were checked, with outliers being visually assessed using a boxplot. To determine whether the data were normally distributed, a Q–Q plot was drafted and the Shapiro–Wilk test for normality was executed. The Mann–Whitney U test was used to analyze statistical significance. Lastly, distribution scores were visually checked with the population pyramids to determine if the distribution was similarly shaped.

Results

A total of 108 patients were enrolled between September 2016 and January 2018 (Fig. 1). Eight patients were withdrawn from the study and replaced. Four patients were withdrawn due to conversion to open surgery and four were withdrawn for logistical reasons. One laparoscopic sigmoid resection was converted to open surgery in the robotic group. This was due to ingrowth of the tumor in the abdominal wall (pT4), which was not detected on the preoperative CT-scan (cT3). Three laparoscopic cholecystectomies were converted to an open approach since the anatomical overview was not complete; the critical view of safety could not be obtained in these cases. Of these three converted procedures, two were found in the robotic group and one was recorded in the control group. No technical failures were reported in the robotic group. One patient was excluded prior to surgery because of weight gain between the outpatient clinic visit and the day of the surgical procedure, which led to exceeding the cut-off BMI limit of 35 kg/m^2. Two patients were excluded due to unavailability of the system, which was in use in another operating room at the time of the surgery. One patient was excluded because the system was not compatible with the operating table of the vascular endosuite operating room.

In the final analysis, the robotic group and the control group consisted of 50 patients each. The demographic data of the patients are shown in Table 1. No significant differences between the two groups were observed in terms of American Society of Anesthesiologists (ASA) classification, age, BMI and gender.

A total of nine right hemicolectomies (five robotic, four control), seven sigmoid resections (three robotic, four control), 43 fundoplications (21 robotic, 22 control) and 41 cholecystectomies (21 robotic, 20 control) were performed (Table 2). A total of 49/50 procedures in the robotic group were performed without human camera assistance, reducing the surgical team size from four to three members. During one laparoscopic fundoplication the robotic system interfered with the left working trocar. The surgeon was unable to continue and the procedure was completed laparoscopically with a human camera assistant. In this case, a fourth member (an extra circulating nurse) was required to complete the procedure. None of the procedures in the control group could be performed with three surgical team members. All were carried out with a surgical team size of four members. The median total operative time for the robotic group was 60.0 min (IQR = 19 min) and for the control group 53.0 min (IQR = 19 min, $p = 0.122$). The median operative time per procedure showed no statistically significant difference between the robotic group and control group. The median operative time of each procedure was: right hemicolectomy 84.0 min vs 67.5 min ($p = 0.462$); sigmoid resection 59.0 versus 74.0 min ($p = 0.289$); fundoplication 69.0 versus 56.5 min ($p = 0.058$); and cholecystectomy 50.2 versus 47.6 min ($p = 0.418$).

The median number of cleaning events were similar in both groups, 2.0 events (robotic) versus 2.0 events (control) per procedure. Most of the cleaning moments were due to fogging of the scope, primarily at the beginning of the operation. Smearing the lens due to tissue contact was rarely seen in the robotic group, slightly less than in the control group. Two adverse events occurred during the study; a reoperation because of bleeding from the gallbladder fossa (robotic group) and readmission because of postoperative pain one week after a cholecystectomy (control group).

The PSSUQ showed positive user satisfaction of the robotic system. The overall score of the system was 2.62, reflecting strong user acceptance of the system. The sub scores of the PSSUQ revealed a system usefulness score of 2.45, a system information quality score of 2.63 and an interface quality score of 3.00. A more detailed breakdown of the system usefulness score showed that the surgeons found the system easy to use (2.70), simple to use (2.50), comfortable (2.10) and easy to learn (2.30). Furthermore, the questionnaire demonstrated that the surgeons could complete their task quickly (2.60) and could become productive quickly (2.50).

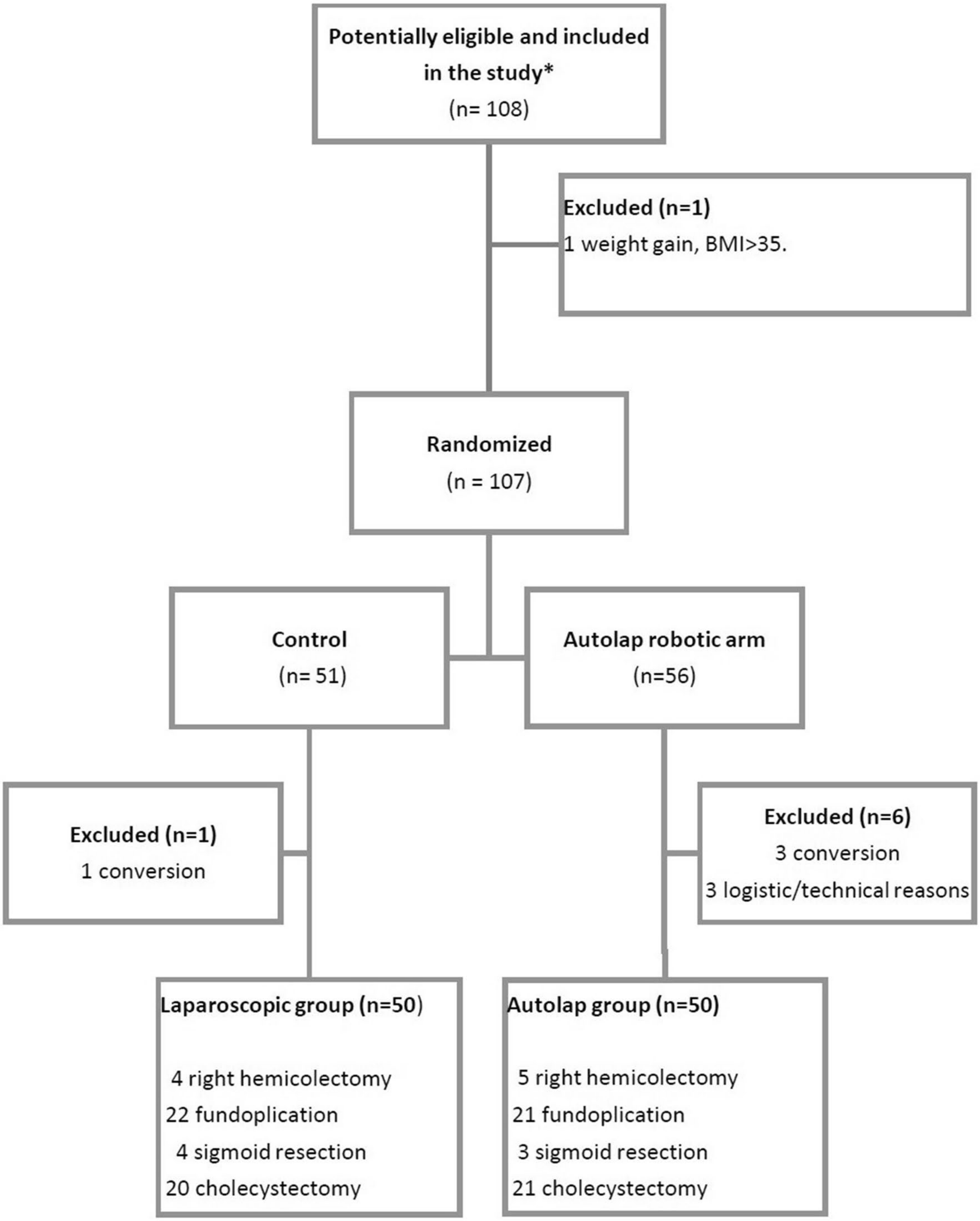

Fig. 1 Study flowchart. *Patients scheduled for a right hemicolectomy, sigmoid resection, fundoplication, and cholecystectomy seen at the outpatient clinic by our clinical investigator during the study period were considered eligible

Discussion

Image-guided robotic camera control was possible in 98% of the cases, reducing the surgical team size from four to three members. Furthermore, there was no significant difference in median total operative time for common general surgery procedures using image-guided robotic camera control compared to human camera assistance. The user experience of the robotic system was positive and the overall performance was good. No technical adverse events occurred.

Our findings are in accordance with previous studies on robotic camera holders [3, 4, 7, 15–19]. These studies

Table 1 The demographic data of the patients

Median values	ASA	Age (years)	BMI (kg/m^2)	Gender female (%)
Robotic group ($n = 50$)	2.00	60.00	26.36	64%
Control group ($n = 50$)	2.00	51.50	26.87	56%
p value	0.642	0.068	0.379	0.417

Table 2 An overview of the number of procedures performed and OR time displayed (median values)

Surgery type	*N*	OR time (min) Median	IQR
Right hemicolectomy	9	74.00	32.50
Robotic group	5	84.00	58.00
Control group	4	67.50	26.00
p value		0.462	
Sigmoid resection	7	66.00	21.00
Robotic group	3	59.00	–
Control group	4	74.00	44.00
p value		0.289	
Fundoplication	43	63.00	24.00
Robotic group	21	69.00	20.00
Control group	22	56.50	22.00
p value		0.058	
Cholecystectomy	41	48.00	19.00
Robotic group	21	51.00	19.00
Control group	20	48.00	14.00
p value		0.418	
Total	100	57.50	20.75
Robotic group	50	60.00	19.00
Control group	50	53.00	19.00
p value		0.122	

have shown that robotic camera assistance is safe and that robotic camera holders enable the ability to perform laparoscopic procedures without camera assistance. However, most of these studies were descriptive and retrospective. To date, three randomized controlled studies have focused on robotic versus human camera assistance in general surgery [1, 3, 20]. Kraft et al. allocated 120 patients planned for laparoscopic cholecystectomy or laparoscopic hernioplasty randomly to robotic camera assistance and manual camera assistance. The study group examined the feasibility of the voice controlled Automated Endoscopic System for Optical Positioning (AESOP) 3000 robot system and concluded that, with the use of the AESOP, laparoscopic surgery was possible in 94% of the cases. However, the authors commented on loss of comfort and prolonged procedure times when using the robotic camera holder. The two other RCTs evaluated the implementation of a robotic camera holder on cholecystectomies exclusively. Aiono et al. ($n = 86$) investigated the EndoAssist, a robotic camera holder controlled by an infrared headset. Gillen et al. ($n = 123$) reported on the joystick controlled SoloAssist system. Both study groups concluded that robotic camera holders are practical, reliable and can reduce personnel. Using robotic camera assistance, Aiono and colleagues reported significantly reduced operating times compared to manual camera assistance. However, Gillen et al. showed prolonged procedure times that could not be attributed to the preparation, setup and demounting time of the robotic camera holder. In this study, evaluation of the median total procedure time showed a tendency towards a prolonged procedure time of 7 min in the robotic group. Although this was not statistically significant, it could be explained by the time used for docking and draping the robotic system. With an experienced team the preparation and setup of the robotic system could be minimized to 4–5 min [12, 21].

The current methods of controlling robotic camera holders allow only simple commands. This results in perpendicular movements that are constrained to only one axis (*X* or *Y*) at a time. A certain amount of attention, concentration and time of the surgeon is thereby required to control the camera. This time is not spent on performing the operation and disrupts the surgeons working flow. It is clear that high level commands and enhanced control capabilities could be of major value in the applicability of robotic camera holders. Image-guided steering is fundamentally different from the current steering methods: instead of perpendicular movements on one axis, the camera is moved on two axes (*X* and *Y*) at the same time. It offers the advantages of intuitive control as the camera is repositioned to the desired location with one click on a joystick, resulting in more fluent and natural camera movements.

There are several important advantages to using robotic camera holders in standardized laparoscopic procedures. Firstly, robotic camera holders provide a stable view of the operative field and improve ergonomics in the operation theater [8, 21]. Secondly, it eliminates the need for a camera assistant and control of the camera is therefore no longer variable and dependent on the experience of the assistant. Additionally, the surgeon is in direct control of the camera and will only make desired movements. In this study, the surgeons scored image-guided camera control as easy and safe to use. Working with the robotic system scored positively on all parameters of the PSSUQ questionnaire.

Shortage of skilled theatre personnel remains an increasing problem worldwide. In our study, the success rate for performing solo surgery was 98%. This can reduce the number of theatre staff members and could eventually lead to increased efficiency and cost reduction. Previous studies have demonstrated solo surgery with robotic camera holders to be cost beneficial [3, 4, 7, 15–17, 19]. Stott et al. demonstrated that the use of the Freehand camera holder was economically viable when performing laparoscopic liver resections. Their robotic system enabled cost savings compared with surgical trainees and surgical care practitioners [22]. However, it is unknown whether these findings can be extrapolated to the use of other robotic camera holders, since purchase costs, maintenance costs and cost per case vary. Furthermore, the cost reduction does not fully apply in a teaching facility, where camera steering is a learning experience for residents. In this study, cost-effectiveness was not investigated.

The conversion rate of 7.3% in the laparoscopic cholecystectomy group was relatively high in this study, however comparable with reported rates in the literature (range: 2.6–7.7%) [23]. Two of the conversions were in the robotic group, one in the control group. None of these conversions were system related, but all were due to failure of anatomical identification of Calot's triangle. Severe inflammation caused by ongoing cholecystitis was the most likely cause for the conversions to open surgery. The operative time of the colectomies were relatively short compared to literature. In two recent systematic reviews longer operative times are reported [24, 25]. Our hospital is dedicated to colonic surgery and the procedures were all performed by three surgeons with extensive laparoscopic colorectal experience, which explains these data.

The strength of this study is the prospective randomized data collection and the heterogeneity of the investigated laparoscopic procedures. This is the first randomized controlled study investigating the ability to perform gallbladder, colonic and fundoplication surgery with a robotic camera holder. The included procedures are a good reflection of the daily practice in an operating room.

The experience of the human camera assistant differed from unexperienced interns to senior residents. Increased experience often leads to more stable and faster camera movements. Furthermore, the team performance of a surgeon and an assistant is much more uneventful when the assistant is familiar with the procedure and the surgical anatomy [6]. Nonetheless, varying camera control experience reflects the daily practice in a teaching hospital. In this study, the camera steering assistants were mainly senior residents in complex procedures and interns in less complex procedures. Therefore, one could argue that the use of inexperienced camera assistants has influenced our results. However, we could not observe significant differences in operative time between complex and less complex procedures.

Most likely, other factors beyond camera steering contribute to operative time, including surgical expertise, surgical fatigue, surgical instruments, patient characteristics and case complexity. We have tried to minimize this effect by only including elective surgeries, choosing well-defined cases and using stratified block randomization. Our analysis was limited by the variables presented, so we could not adjust for the potential confounding impact of these factors.

A first-generation robotic system was used in this study that had some shortcomings. Firstly, the size of the system and docking procedure of the system were not fully optimized. Therefore, the setup was occasionally cumbersome and time-consuming. The surgeon was not able to (re)position the system without assistance and a circulating nurse was essential during the setup of the system. Next generations of image-guided robotic camera holders should ideally have a smaller footprint in order to optimize the docking and draping. These shortcomings are also reported by Rade et al. [21] Another drawback is the parallelogram design of the robotic system. This limited the movement range of the camera, which was mainly observed during colectomies and resulted occasionally in repositioning of the system during surgery [17]. Improving the range of motion will allow for easier access to a wider surgical field and is essential for future robotic camera holders in order to perform laparoscopic surgery in multiple quadrants.

Conclusion

This study demonstrated the ability to perform cholecystectomies, right and left colectomy procedures and fundoplications with image-guided robotic camera assistance. This reduced the surgical team size from four to three members and did not result in a significant increase in operative time and. Image-guided camera control was found to be comfortable and satisfactory. Future developments of the system could lead to increased acceptance and use of robotic camera holders.

Disclosures

P.J.M. Wijsman was a Clinical Field Engineer of Medical Surgery Technologies ltd (M.S.T.) from 2016 to 2018. I.A.M.J. Broeders is a consultant for Johnson & Johnson and Intuitive Surgical. F.J. Voskens, L. Molenaar, C.D.P. van'tHullenaar, E.C.J. Consten and W.A. Draaisma have no conflicts of interest or financial ties to disclose.

Acknowledgements We are very grateful to Mr. Michael Orrell from Oxford University Hospitals. We would like to thank him for his advice and comments relating to the English language and grammar used in this manuscript.

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