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A Prospective, single arm study on the use of the *da Vinci*[®] Table Motion with the Trumpf TS7000dV operating table

Running head: Robotic Surgery and da Vinci Table Motion

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ABSTRACT

Background: The da Vinci[®] Table Motion (dVTM) comprises a combination of a unique operating table (Trumpf Medical[™] TruSystem[®] 7000dV) capable of isocenter motion connected wirelessly with the *da Vinci Xi*[®] robotic platform, thereby enabling patients to be repositioned without removal of instruments and or undocking the robot.

Materials and Methods: Between May 2015 to October 2015, the first human use of dVTM was carried out in this prospective, single arm, post-market study in the EU, for which 40 patients from general surgery (GS), urology (U) or gynecology (G) were enrolled prospectively. Primary end-points of the study were dVTM feasibility, efficacy and safety.

Results: Surgeons from the three specialties obtained targeting success and the required table positioning in all cases. Table movement/repositioning was necessary to gain exposure of the operating field in 106/116 table moves (91.3%), change target in 2/116 table moves (1.7%), achieve hemodynamic relief in 4/116 table moves (3.5%), and improve external access for tumor removal in 4/116 table moves (3.5%). There was a significantly higher use of tilt and tilt plus Trendelenberg in GS group (GS versus U $p=0.055$ and GS versus G $p=0.054$). There were no dVTM safety-related or adverse events.

Conclusions: The dVTM with TruSystem 7000dV operating table in wireless communication with the da Vinci Xi is a perfectly safe and effective synergistic combination, which allows repositioning of the patient whenever needed without imposing any delay in the execution of the operation. Moreover, it is helpful in avoiding extreme positions and enables the anesthesiologist to provide immediate and effective hemodynamic relief to the patient when needed.

Keywords: da Vinci Xi; Robotic surgery; da Vinci Table Motion; dVTM

INTRODUCTION

The execution of minimally invasive surgery (MIS), particularly in general surgery, gynecology, and urology has been improved by the *da Vinci* system (Intuitive Surgical, Sunnyvale, CA, USA) [1, 2].

The robotic platform provides a stable camera view to identify vessels, nerves and musculo-fascial structures and allows for counter traction under the surgeons' control, which together with Endo-Wrist enables fine and precise movements even in narrow spaces such as the pelvis [3].

Unlike open surgery where tissues can be actively retracted by hand, the ability to retract tissues and displace organs is limited in MIS. The challenge in visualizing and gaining access to the operative field in laparoscopic surgery can be reduced with the use of gravity to assist in gaining exposure through changes in the patient's position on the operating table and by the tilt of the table itself e.g., Trendelenburg position or lateral tilt.

During robotic-assisted surgery (RAS), the inability to alter the position of the patient without undocking the robot, limits operative flexibility and thus adds to the operative time. This becomes an issue in multi-quadrant and pelvic surgery [4]. For instance, lymph node dissection [5], colon mobilization [6], bilateral organ removal [7], and nephroureterectomy [8] often involve changing the intra-operative position of the patient and/or robot. Sometimes this issue necessitates a hybrid approach, or enforced conversion to traditional direct manual laparoscopic or open surgery. Undocking the robot involves interrupting the operation to remove the instruments, and undock the manipulator arms from each of the cannulas before repositioning the patient; followed by re-docking the manipulator arms to each of the cannulas, re-inserting the instruments before resuming the operation. The disruption of the surgical work flow is the major cause for prolonging the OR time [8-11].

The TruSystem 7000dV Operating Table (TS7000dV, TRUMPF Medizin Systeme GmbH & Co. KG, Saalfeld, Germany) is a remotely controlled, adjustable operating table designed to work wirelessly with the *da Vinci Xi* Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA) to provide integrated table motion (dVTM) during surgery (Figure 1). This dVTM provides coordinated movement of the patient and the surgical instruments which allows altering the patient's position, without the need for undocking. This gives the surgeon the flexibility to re-position the patient without interrupting the flow of the operation. It also enables more effective gravity-induced exposure of the operative field at the desired working plane [12]; with the added benefit of providing immediate patient relief in cases where Trendelenburg tilt is not well tolerated by the patient. The purpose of the present study is to evaluate the feasibility, efficacy and safety of dVTM in performing RAS operations across the three specialties of general surgery (GS), gynecology (G), and urology (U).

MATERIALS AND METHODS

Between May 2015 and October 2015, the first human use of dVTM was carried out in a prospective single center, single arm post-market study in the EU, for which 40 consecutive cases from three surgical specialties (GS, G, U) were enrolled prospectively. The study was approved by the Institutional Ethics Committee. During the study period, all patients eligible for minimally invasive surgery meeting the inclusion and exclusion criteria of the study, were put on the waiting list of the three surgical specialties involved and enrolled in the study for which a study-specific informed consent was obtained in writing from each patient.

The inclusion criteria were: body mass index ≤ 45 kg/m²; age 18 years or older; suitable for minimally invasive surgery; ability to tolerate the Trendelenburg position; willingness to participate. The exclusion criteria were American Society of Anesthesiologists (ASA) IV patients; pregnancy; lack of cooperation due to psychological or severe systemic illness; comorbid medical conditions contraindicating general anesthesia; anatomy unsuitable for endoscopic visualization or minimally invasive surgery; patient not compatible with the Trumpf TS7000dV operating table due to weight >1000 lbs., allergy to table material, stature not fitting on table, inability for re-positioning during surgery, or inability for robotic docking.

The patients were recruited from three specialties: general surgery (GS), urology (U) and gynecology (G). The two sub-groups of GS were colorectal operations (GS-CR) and patients undergoing other general surgery operations (GS non-CR). Furthermore, we identified three groups based on the number of anatomical targets per single operation, regardless of specialty: procedures with one anatomical target (AnTG1), procedures with two anatomical targets (AnTG2) and in procedures with three or more anatomical targets (AnTG3).

Primary end-points were dVTM feasibility, efficacy, and safety. Feasibility and efficacy were evaluated by assessing the ability to complete the procedure and using dVTM to attain necessary surgical exposure without undocking the robot. For this purpose, the number of dVTM moves made per case were recorded, together with duration of every table move, time to attain desired table position, reasons for moving the table, and location of the instruments and endoscope, (inserted or removed) during table moves. The safety of dVTM was evaluated by analyzing patient vital data (pre- and postoperative mean blood pressure and heart rate), estimated blood loss, urine volume, total administered fluid, port-site condition, intra and postoperative complications, adverse events related to the use of dVTM (incidence of tissue/nerve/organ injuries) and discharge date. Pre-operative assessments included patient demographics and baseline/pre-operative clinical parameters: gender age, BMI, co-morbidities, ASA score, prior surgical history and pre-operative diagnosis.

The collected intraoperative data were operative room time, anesthesia start/stop time, operative time, blood loss, transfusions, conversions, IV fluids administered, pre-procedure and intra-procedure patient

vital signs, number of targets per procedure, targeting success, number of moves per case, duration of each table move, and time to attain the table position (Trendelenberg, reverse Trendelenberg and left/right tilt). In addition, the grade of table motion, reasons for moving table and location of instruments and laparoscope (inserted or removed) during table move, any table-related interruptions and any intra-operative complications related to the surgery or to table moves. Intra-operative complications recorded included external tissue and internal tissue injuries, nerve injuries, hemodynamic stability related to fluctuations in blood pressure or changes in respiratory or ventilation pressures, excessive bleeding or hemorrhage requiring intervention, neurologic stability related to ocular or neuromuscular injury and patient stability during various positions including sliding on the table, cannulas moving in or slipping out of the peritoneal cavity, or insufflation issues during table motion.

Post-surgical assessment before discharge included: port-site wound condition for any discoloration, ischemia, subcutaneous emphysema, expansion or other post-surgical complications. Daily postoperative vital signs, urine volume and estimated blood loss was also being recorded from all patients included in the study.

A follow-up visit (2-4 weeks after surgery), was conducted to assess the patient's general well-being and record any complications/adverse events since discharge.

Device notes

The TruSystem 7000dV operating table can interact with the da Vinci Xi surgical system to support dVTM, enabling table motion with the robotic side-cart while it is docked (attached) to cannulas inside the patient (Figure 1). The operating table is an optional third-party auxiliary product for use with the da Vinci Xi system; it is not required for normal use of the da Vinci Xi system. Two types of wireless interfaces (infrared and radio frequency) enable communication between the table interface module (TIM) in the da Vinci Xi system and the operating table. A remote connected to the table via cable is used by surgical staff to command table motion (Figure 2). The dVTM allows the surgical staff to reposition the patient by adjusting the table while still docked to the da Vinci Xi surgical system. When users turn on dVTM, the set-up joint brakes release on the da Vinci Xi system's patient cart, allowing the instrument arms to passively and safely move with the patient. If instruments remain on the arms during the motion, the surgeon must have them in view and under active control for the table motion to be allowed. When users turn off dVTM, the joint brakes reapply, and the arms return to typical surgical use. If the joints reach a range of motion limit during dVTM, the boom compensates by moving in a direction that gives the arms additional range of motion (Figure 1). If the boom or the table reach range of motion limits, all motion is stopped.

Statistical analysis

Analyses were done using the statistical package SPSS®, version 17 (SPSS Inc., Chicago, IL, USA). Variables of interest were prospectively analyzed. Sample characteristics were assessed using descriptive statistics. Continuous variables were expressed as the mean, median and range, whereas categorical variables were expressed as counts and percentages. Non-parametric Kruskal-Wallis test was performed to compare the movements (Trendelenberg movements; Tilt movements and Tilt plus Trendelenberg) between groups (GS, U and G). Subsequently the Non-parametric Mann–Whitney U analysis with Bonferroni correction was performed to verify the difference between the three movements in the comparison of the paired groups (GS and GS-CR versus U and GS and GS-Cr versus G).

Moreover, one-way analysis of variance (ANOVA) was used to examine the difference means of Operating room variables (“Operating room time”, “Robotic time” and “Number of table moves”) among AnTG1, AnTG2 and AnTG3 groups.

Finally, multinomial logistic regression model was used to test simultaneously the combinations of Operating room variables to AnTG classifications.

The AnTG classification was chosen as the dependent variable comparing “AnTG2” and “AnTG3” to “AnTG1” classifications, while the independent variables were “Operating room time”, “Robotic time” and “Number of table moves” variables. All p values were 2-sided and considered statistically significant if $p < 0.05$.

RESULTS

Demographic characteristics and preoperative conditions of the enrolled patients are summarized in Table 1. Of the forty cases 15 were GS patients (7 anterior rectal resections, 2 right colectomies, 1 sigmoidectomy, 1 liver resection, 1 subtotal gastrectomy, 1 partial pancreatectomy, 1 ventral rectopexy and 1 abdominal hernia repair), 13 were U patients (9 prostatectomies, 1 nephrectomy, 2 partial nephrectomies and 1 pyelo-ureteral junction plastic) and 12 were G patients (10 hysterectomies, 2 pelvic organs prolapse repairs). In GS group, there were 2 procedures with one anatomical target and 13 procedures with two or more anatomical targets while in U and G group there were 7 and 5 procedures respectively with one anatomical target, and 6 and 7 with respectively two or more anatomical targets.

Operative and dVTM overall results

Mean operating room time (ORT) was 229 min (median 215 min, range 57–70 min), mean anesthesia start/stop time (AT) was 290 min (median 262.5 min, range 68–120 min), and mean robotic time (RT) was 169 min (median 150 min, range 39–25 min). Targeting success was achieved in all cases. The mean number of table moves was 2.9 (median 2, range 1–6), resulting in 116 instances of table moves in 40 procedures. The mean duration of each table motion was 69.03 seconds (median 43.5 seconds, range

401-5 seconds). The desired table position was attained in all cases. The reason for moving the table was to gain internal exposure of the operating field in 106/116 table moves (91.3%), to change target in 2/116 table moves (1.7%), to achieve hemodynamic relief in 4/116 table moves (3.5%) and to improve external access and allow tumor removal in 4/116 table moves (3.5%). The endoscope was left inserted during 113 of the 116 table movements (97.4%), and the instruments were left inserted during 101 of the 116 table movements (87%). The table movements duration was less than 2 minutes per move in 100 of 116 of moves (86.2%). Mean estimated blood loss was 156.75 ml (median 40 ml, range 1100–10 ml), mean urine volume was 711.25 ml (median 525 ml, range 2000–300 ml), and mean total volume of administered fluid was 2837 ml (median 3000 ml, range 6000–1500 ml). The mean pre- and post-operative blood pressure was 78.25/141.75 mmHg (median 80/140 mmHg, range 95/180–50/105 mmHg) and 71.75/123.88 mmHg (median 70/125 mmHg, range 95/155–50/90 mmHg) respectively. The mean pre- and post-operative heart rate was 69.13 bpm (median 70 bpm, range 110–45 bpm) and 65 bpm (median 67.5 bpm, range 80–45 bpm), respectively.

The mean length of hospital stay was 6.2 days (median 4 days, range 60–2 days). The port site wound was undamaged in all cases. No external instrument collisions or other problems related to the operating table were encountered. There were no dVTM-related intra- or post-operative complications. In one patient, it was necessary to convert to laparotomy because of major bleeding unrelated to use of the table. There were no dVTM safety-related observations and no adverse events. Data of each specialty group/subgroups and table position are summarized in tables 2-5.

Comparative results within specialties and AnTG groups

Comparing the three movements among the groups (GS versus U and GS versus G) there was a higher use of tilt and tilt plus Trendelenberg in GS group with a statistically significant difference (GS versus U $p = 0.055$ and GS versus G $p = 0.54$). This difference was more pronounced in the subgroup GS-CR (GS-CR versus U $p = 0.0044$ and GS-CR versus G $p = 0.0038$). In GS group, there were 6 table left/right tilt movements $> 20^\circ$ and 14 table Trendelenberg/Reverse Trendelenberg movements $> 20^\circ$, 6 table left/right tilt movements in GS-CR subgroups. In U and G groups there were no table left/right tilt movements with more than 20° . In the U and G groups, were 17 and 18 table Trendelenberg/Reverse Trendelenburg moves $> 20^\circ$ respectively.

The AnTG1 group included 1 liver resection, 1 nephrectomy, 2 partial nephrectomies, 1 pyelo-ureteral junction plastic, 1 abdominal hernia repair, 5 hysterectomies, 3 prostatectomies. The AnTG2 group includes 1 left pancreatectomy, 2 right colectomies, 1 sigmoidectomy, 3 pelvic organs prolapse repairs/ventral rectopexy, 1 subtotal gastrectomy. The AnTG3 group included 6 prostatectomies with lymphadenectomy, 7 anterior rectal resections, 5 hysterectomies with pelvic lymphadenectomy the mean number of table moves in AnTG1 was 1.7 ± 0.6 , with 24 table moves in 14 procedures. In the AnTG2,

the mean table moves averaged 3.88 ± 1.45 , with 31 table moves in 18 procedures. In AnTG3 he means was 3.39 ± 1.50 , with 61 table moves in 18 procedures. There was a higher number of table moves in AnTG2 and AnTG3 than in AnTG ($p = 0.001$) (Fig.2). Multivariate multinomial logistic regression showed that “AnTG2” and “AnTG3” groups had a significantly higher number of table moves than “AnTG1” (AnTG2; OR: 6.82; CI, 1.42-22.794; AnTG3; OR: 5.50; CI, 1.216-25.084) (Fig.3). No statistically significant association was observed respect to the Operating room time and Robotic time.

DISCUSSION

Robotic-assisted surgery (RAS) provides significant advantages over direct manual laparoscopic surgery (DMLS) including stable camera view of the operative field, fine and precise movements in confined spaces and a shorter proficiency-gain curve. However, the robotic approach also has some drawbacks, e.g., lack of tactile feedback, bulk, and maneuverability of robotic arms, and most importantly, problems in execution of multiquadrant operations.

The latest robotic platform by Intuitive Surgical Systems, the da Vinci Xi, was developed specifically to overcome these limitations by a new overhead architecture that combines the functionality of a boom-mounted system with the flexibility of a mobile platform [13, 14]. Although the maneuverability of the Xi da Vinci system, particularly for execution of multiquadrant operations, appears superior to its Si precursor, the fixed patient position when docked to the robot limits the working space [15]. Undocking, instrument extraction, and cart repositioning although simplified, remain necessary for safe exposure of the operative field, thereby increasing the operative time. In this respect the Xi da Vinci is no better than the previous da Vinci Si.

A docked da Vinci System Si or Xi prevents the OR team to reposition the patient by gravity, easily obtained in DMLS, since safe repositioning of the patient requires undocking and re-docking the robot, which is time-consuming [8-11]. Reducing the OR time during RAS is not only relevant for patient safety, but also carries economic advantages, especially in major multidisciplinary centres where use by several specialties and surgical units on a booking basis increases the financial sustainability of RAS. The dVTM was specifically developed to address this issue by enabling table motion with instrument in place and without undocking, thus maximizing the benefits of RAS performed by the da Vinci Xi [15].

The first two primary endpoints of the present study, feasibility and efficacy have been demonstrated by the ability to complete the procedure with the Xi in combination with dVTM to obtain uninterrupted surgical exposure throughout the operation without undocking the robot in all the 40 enrolled cases. The safety of the combination was demonstrated by the absence of adverse dVTM related events.

This initial experience with dVTM combination was entirely positive because it allowed seamless execution of the procedure whenever patient repositioning was needed. Moreover, this was achieved in complete safety and without any evidence of damage to the port wounds. This advantage was

encountered by all procedures, but carries special benefit in multiquadrant operations requiring several table moves to reposition the patient. The reduced operating time aside from benefitting the patients, facilitates cost effective scheduling and increases cost efficacy of RAS. Another benefit consequent on the use of dVTM during RAS with the da Vinci Xi relates to safe gravity exposure providing quick access to different surgical objectives without the need to undock the Xi, i.e., with a full-robotic approach in all cases. The dVTM enables what is best described as '*controlled graded gravity exposure*' (CoGGE) by regulating the Trendelenburg and/or lateral tilt precisely and not beyond the required tilt.

Differences were documented between the specialties. Thus, in the GS group, and especially the GS-CR sub-group, there was a statistically significant greater combined lateral tilt with Trendelenburg table moves compared with G and U. In most cases in the GS-CR, significantly more table moves were required to obtain table tilts exceeding 20° to gain exposure of the operative field during the different phases of the operation. This result is due to a greater need to change the exposure of the surgical field in different quadrants of the abdominal cavity, (splenic flexure to inferior mesenteric vessels and pelvis for rectal cancer surgery), and from ileo-colic junction to transverse colon for right colectomy), because of greater need for combined lateral and upper/lower quadrant exposure. These data agree with those previously published by our group in a preliminary series of the colorectal group alone [12].

In the G group, many table moves, especially pure Trendelenburg ones, were required to obtain surgical exposure of central pelvis, usually with moderate < 20 ° tilt, and were associated mainly with lateral pelvic reach for lymph node dissection. Pure Trendelenburg was used for exposure of deep pelvic spaces during operations for pelvic organ prolapse and simple hysterectomies. Moderate tilt was needed to displace the sigmoid colon during rectal prolapse surgery and for lateral lymph node dissection in radical hysterectomies for cancer. A similar pattern of use was observed during pelvic urological procedures to optimize exposure during prostatectomies with or without left/right tilt, depending on need or otherwise for lymph nodes dissection.

These differences between the three groups reflect the nature of the operations performed. Thus, many operations in GS, and especially GS-CR, are largely multiquadrant operations, for which dVTM is essential for efficient cost and effective execution of the operations avoiding unproductive interruptions of the operation incurring substantial extra operating time. In contrast, G and U operations are mainly single quadrant procedures, the principal use for dVTM being to optimize gravity exposure, and avoid extreme positions with the CoGGE technique described above, and to improve exposure of lateral pelvic spaces during lymph node dissection [16].

The optimization of gravity exposure by the CoGGE technique with graded incremental tilt and stopping when exposure is reached, thereby avoiding unnecessary use of extreme positions, should increase patient's safety, not only in hemodynamic terms, but also by preventing increased intraocular pressure, neurologic or soft tissue injuries. With dVTM and the technique described, no adverse hemodynamic

changes were observed during the operations. In 4 cases (3.5%) dVTM was used to achieve hemodynamic relief. The dVTM gives the anesthesiologist the ability to precisely control patient positioning and display the table position to the entire surgical team including the degree of Trendelenburg tilt on the remote monitor, Vision System Cart monitor, and Surgeon Side Console monitor.

We acknowledge the limitations of the present pilot study including its observational nature, small sample size, the heterogeneous surgical operations, the lack of a control group, and the different experience in RAS by the participating surgeons. Hence although the results are very encouraging, they need confirmation by larger studies, preferably within the context of a prospective RCT and such a trial should also include health economic endpoints.

CONCLUSIONS

The present study has confirmed the benefit and safety of RAS with the dVTM enabling operations requiring repositioning of the patient without disruption of the procedure, which would otherwise be needed to undock/ redock the robot and remove/ reinsert instruments from the peritoneal cavity. The study has shown that the greatest benefit from the use of the dVTM is observed in multi-quadrant surgery exemplified by the GS and especially GS-CR operations. The possibility offered by the dVTM limit or avoid extreme positions for optimal exposure of the operative field and may reduce patient morbidity.

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Conflict of interest: Prof. Morelli Luca, Dr. Palmeri Matteo, Prof. Simoncini Tommaso, Dr. Cela Vito, Dr. Perutelli Alessandra, Prof. Selli Cesare, Dr. Bucciante Piero, Dr. Francesca Francesco, Dr. Cecchi Massimo, Dr. Zirafa Cristina, Dr. Bastiani Luca, Prof. Cuschieri Alfred and Dr. Melfi Franca have no conflicts of interest or financial ties to disclose.

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Figure Legends

Figure 1: Illustration of the da Vinci[®] Table Motion (dVTM) for the da Vinci Xi surgical system (Intuitive Surgical Inc., Sunnyvale, CA, USA). dVTM is a new feature comprising a unique operating table by Trumpf Medical Systems that communicates wirelessly with the da Vinci Xi. The da Vinci Xi surgical system and the TruSystem 7000dV operating table (TS7000dV, TRUMPF Medizin Systeme GmbH & Co. KG, Saalfeld, Germany)

Figure 2: One-way analysis of variance (ANOVA) of number of table moves among AnTG1, AnTG2 and AnTG3 groups.

Figure 3: Multinomial logistic regression model was used to test simultaneously the combinations of Operating room variables (“Operating room time”, “Robotic time” and “Number of table moves”) to AnTG classifications.