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Article

Early Clinical Outcomes of the Novel Hinotori Robotic System in Urological Surgery

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Abstract: Introduction: The advances in urological surgery across the decade has continued to burgeon, particularly in the pursuit of minimally invasive approaches for major operations. Robotic-assisted surgery has gradually established its role in uro-oncological cases that demand a high level of precision, optimising surgeon ergonomics and decreasing fatigue whilst maintaining optimal clinical outcomes. With the novel Hinotori surgical robot (Medicaroid Corporation (Kobe, Hyogo, Japan) launched in Japan back in 2019, it has now demonstrated its use case across various clinical series of different surgeries. We sought to narratively synthesise the initial feasibility of the Hinotori robotic system in Urology. Methods and Results: A non-systematic, comprehensive literature search was conducted across various databases from September 2024 to October 2024. Relevant keywords within the scope of this study were generated for a more accurate search. After exclusion and removal of duplicates, a total of nine articles that encompassed a diverse range of urological surgeries were included for review. Among the included studies, one study reported data solely on radical prostatectomy for prostate cancer, two studies reported on robotic-assisted nephroureterectomy for renal tumors, two studies on partial nephrectomy performed for renal masses, two studies reported on radical nephrectomy carried out for renal malignancies and one study on robotic-assisted adrenalectomy for adrenal cancer. Lastly, one study collectively reported on outcomes pertaining to partial nephrectomy, partial nephrectomy, vesicourethral anastomosis and pelvic lymph node dissection in porcine, as well as partial nephrectomy, radical prostatectomy and pelvic lymph node dissection in cadavers. Conclusion: The new Hinotori robotic system offers unique three-dimensional features as a non-inferior robotic platform alternative that has proven clinically safe thus far in its use. Larger scale studies and randomised trials are eagerly awaited to assess and validate more holistically its clinical utility.

Keywords: robotic surgery; hinotori; urology

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1. Introduction

Urology has welcomed its era of minimally invasive surgery in the recent decade – with the shift from traditional open surgeries to laparoscopic and robotic-assisted surgeries, cases with complex anatomy requiring sophisticated planning are made less challenging. The Da Vinci Robotic System developed by Intuitive Surgical Inc. (Sunnyvale, California, USA) has been one of the pioneers and remains highly utilized till date. However, although uncommon, complications pertaining to Da Vinci have been reported in the form of morbidity and mortality-related events. Healthcare technology companies hence continue their efforts in refining the existing robotic platforms in attempts to account for these shortcomings. Within the region of Asia, the Hinotori Robotic System produced by Medicaroid Corporation (Kobe, Japan) has primed itself as one of the rising competitors in robotic surgery. Officially approved for clinical use in August 2020, Hinotori has successfully witnessed its application in routine surgical practice. Features that set it apart from current robotic platforms in the market include an additional axis of motion (8 axes of motion), while maintaining

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its compactness and minimizing interference between working arms. It also features a docking-free design, which confers increased flexibility of the robotic arm once the dedicated surgical instrument is attached. This reduces extra-corporeal interference within the operating field. Owing to its relative nascency, the Hinotori platform has only been formally utilized in Japanese cohorts. The aim of this study is to narratively synthesize the literature reported on Hinotori till date and summarize the clinical outcomes associated with its initial years of application.

2. Methods

A search was carried out across multiple databases from December 2023 to February 2024, with the search terms ''Hinotori'', ''Urological Robotic Surgery,'' ''Robotics'' and other terms deemed relevant to the scope of the study. An initial number of 10 articles were included in the initial search. Duplicates were excluded and articles were screened. Studies that focused on other novel robotic platforms were excluded. After exclusion, a total of nine studies were finalized for review. Among the included studies, one study reported data solely on radical prostatectomy for prostate cancer, two studies reported on robotic-assisted nephroureterectomy for renal tumors, two studies on partial nephrectomy performed for renal masses (either benign or malignant), two studies reported on radical nephrectomy carried out for renal malignancies and one study on robotic-assisted adrenalectomy for adrenal cancer. Lastly, one study collectively reported on outcomes pertaining to partial nephrectomy, partial nephrectomy, vesicourethral anastomosis and pelvic lymph node dissection in porcine, as well as partial nephrectomy, radical prostatectomy and pelvic lymph node dissection in cadavers.

3. Results

Baseline characteristics of all studies, including peri-operative indicators and follow-up outcomes post-surgery are detailed in Table 1. In-depth parameters of partial or radical nephrectomies such as preservation of renal function and achievement of trifecta outcomes are provided in Table 2.

3.1. Robotic-assisted Partial Nephrectomy (RAPN)

RAPN has become widely used for treatment of renal cell carcinoma and it is expanding in the field of complex renal masses [1]. In recent years, RAPN has developed to become a safe technique that reduces warm ischemia time (WIT) in comparison to the laparoscopic approach [2]. Currently, the utility of robotic-assisted partial nephrectomy has been well established with the Da Vinci robotic surgical system as the primary platform. Since the advent of Hinotori in Japanese institutions, the novel system has been validated in its use within both the pre-clinical and clinical context. Three studies published on RAPN outcomes using the Hinotori system, with Motoyama et al.'s study acting as a primary comparison with the Da Vinci system and Hinata et al.'s being a cadaveric one [3, 4]. Motoyama et al. published the first clinically matched prospective cohort study - looking at patients with small renal masses (SRM) that underwent RAPN with either the Da Vinci or the novel Hinotori system. Perioperative and oncological outcomes were non-inferior in the Hinotori group, with no significant differences in operative duration and ischemic time seen and no major complications as well. Negative surgical margins were also achieved in all patients. "Trifecta" outcomes were also attained in 100% of patients operated with the Hinotori system and post-operative renal function changes were comparable to that of the Da Vinci cohort. Similar findings were corroborated in a separate study by Miyake et al., who also sought to prospectively evaluate 30 cases of RAPN with the Hinotori robotic system [5]. Zero major complication rates and no positive surgical margins were encountered, alongside full achievement of trifecta parameters as well.

3.2. Robotic-assisted Radical Nephrectomy (RARN)

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Two studies by Motoyama were published on RARN, with one study done with direct comparison to the Da Vinci system and the other focusing on a select group of 2 patients requiring RARN and IVC tumor thrombectomy (IVCTT) with the novel Hinotori system [6, 7]. In the former study, a total of 34 patients (13 Hinotori, 21 Da Vinci) patients underwent RARN as a retrospective case series across both platforms. Both platforms achieved satisfactory peri-operative and post-operative outcomes – no significant differences were found in parameters such as operative duration, estimated blood loss, major complication rates and post-operative length of stay. Negative surgical margins were attained in both groups as well. The RARN/IVCTT study comprised of 2 patients with clear cell renal cell carcinoma (RCC), pT3b, WHO ISUP Grades 3 and 4, with the other RN study focusing on local renal tumors in a larger sample size of 13 patients. Despite the relative anatomical complexity in tackling Level I and II IVC thrombi, the Hinotori system provided optimal outcomes as well, reporting zero major complication rates with any need for intra-operative blood transfusion or conversion to open RN.

3.3. Robotic-assisted Nephroureterectomy (RANU)

The use of RANU is becoming increasingly prevalent [8]. 2 studies have been published to date on RANU using the Hinotori system. In Shimizu et al.'s study, it discusses a case series of 4 cases and in Motoyama et al. study, it describes their experience in 8 patients. In the former study, outcomes were compared in retrospect to their Da Vinci cohort as well, of which demonstrated no significant differences between both groups. There was 1 Clavien-Dindo Grade 3 complication in the Da Vinci group. In terms of trocar placement, an 8-mm robotic port was placed two finger widths below the costal margin at the lateral edge of the rectus muscle, the third arm was placed as close to the midline as possible, and the camera and robotic another arm ports were placed 7cm apart from each robotic arm port. The 12-mm assistant port was placed at least 5cm median from the camera port.

In Motoyama's study, 3 patients underwent RANU for renal pelvic tumours and the remaining 5 patients for lower ureteral tumours [6]. The surgical steps are described as follows: firstly, a nephrectomy starting out from the renal hilum, proceeding onwards to lymph node dissection, vesico-ureteric junction and ureteric dissection, distal ureterectomy, bladder cuff excision, cystostomy and the eventual en-bloc removal of the specimen. Trocar placement was described as a 12 mm camera port (#1), two 8mm ports for a robotic arm on each side - right (#2) and left (#3), two 12mm ports for assisting (#4 and #5) and a final port for liver traction (#6) at the kidney direction stage. At the bladder direction stage, the 3rd and 4th ports are switched. Hence, the 8mm robotic port is placed inside the 12mm port for the left arm and one of the 8mm assisting ports is converted to a 12mm port for assisting. Notably, a difficulty encountered during surgery was that the Hinotori required undocking when moving from the kidney to bladder direction phase to re-determine trocar positioning. Median operating time was 230 minutes, estimated blood loss was 23ml and mean hospital stay was 10 days. There were no postoperative complications. When this was compared to 4 patients who received RANU using Da Vinci, their operative time was 211 minutes and estimated blood loss was 35mls with no major complications, and mean hospital stay was 12 days. Furthermore, these current outcomes were comparable to other studies focusing on RANU using the Da Vinci robotic platform. In study of 5 RANUs performed, operative time was 160–240 minutes, 100-200ml estimated blood loss and 3-7 days of hospital stay [9]. Morizane's study of nine cases undergoing RANU describes the following perioperative outcomes of operative time at 323 minutes; estimated blood loss at 55 mL, length of hospital stay at 12 days and no major complications and length of hospital stay =12 days [10].

3.4. Robotic-assisted Adrenalectomy (RAA)

Most RAAs have substantial evidence in the use of the Da Vinci system but the use of the Hinotori platform in adrenalectomy still has limited evidence. Adrenalectomy is considered a challenging procedure, and the laparoscopic approach is widely accepted traditionally when compared to open surgery [11]. However, conversion to robotic approach has gained traction in

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recent years, and has proven to be highly effective and safe [12-14]. In a meta-analysis by Argusa, RAS is considered superior to a laparoscopic approach due to shorter hospital stay and lesser blood loss [15, 16]. The initial and only study of the Hinotori System by Motoyama discusses a case report of six cases, where adrenalectomy was performed in for adrenal tumour using Hinotori compared to 5 patients using the Da Vinci system [17]. In all 11 patients, they underwent the transperitoneal approach, with no differences in surgical procedures, including the port replacement. In terms of trocar placement, three trocars were used as robotic arms and one to two additional trocars for assisting. This includes AirSeal iFS (CONMED Japan KK, Tokyo, Japan) in patients with left adrenal tumors, or to lift a last trocar to lift the liver lift in patients with right adrenal tumors.

Both groups had similar perioperative outcomes, with a median operative time of 119 minutes, estimated blood loss of 8ml, and length of hospital stay at 7 days. No patients experienced major perioperative complications. The Hinotori group had slightly longer operative times, owing to larger adrenal tumors. Additionally, the Hinotori group had perioperative outcomes like those of other institutions using the Da-Vinci system. To illustrate this using Francis study in 37 patients who underwent RAA, the operative time was 213 minutes, estimated blood loss at 74 mL and length of stay was 1.4 days [12]. Four patients experienced postoperative complications that resulted in unplanned hospital readmissions and there was one mortality.

3.5. Robotic-assisted Radical Prostatectomy (RARP)

Robotic surgery has revolutionised radical prostatectomies in Urology., establishing its use as a superior approach to laparoscopic surgery [18, 19]. 2 studies are published on RARP using the Hinotori system. In Yamamoto's study, 93 patients were included, with two groups, one group using the Da Vinci system and the other group using the Hinotori system [20]. For the Hinotori group, the median operative time was 343 minutes and median blood loss was 180ml, with median console time at 271 minutes. There was 1 perioperative complication of common bile duct stone in this group. When compared to the Da Vinci group, the median operative time was 334 minutes and median blood loss was 172.5ml, with median console time at 254 minutes. There were 2 perioperative complications of common bile duct stone and pulmonary embolism in this group. Regarding trocar placement, it is performed similarly to conventional port placement with 4 robotic arms and 2 assisting ports.

Another study by Hinata reports on RARP performed in 30 patients with localized prostate cancer [4]. Male patients had a pre-operative PSA of 7.6 ng/ml. The following outcomes of median console time and blood loss were 165 min and 162.5 ml, respectively. Significantly, four (13.3%) recoverable errors were observed due to longer operation time because of equipment malfunction, which necessitated recovery time during the operation. Compared to the Da Vinci system, there is a failure rate of 0.5% due to device failure when evaluating over 800 RARPs in a prospective study by Zorn KC et al [21]. Three major perioperative complications (Clavien-Dindo ≥3) were reported, including anastomotic leakage, paralytic ileus, and pulmonary embolism. Post-operatively, positive margins were observed in two out of 26 cases (7.7%) for pT2 diseases and in two out of four cases (50%) for pT3 cancers. Trocars included three ports for robotic arms, one camera port, and two assisting ports. Compared to other robotic systems such as Revo-i, a study of 17 patients reported median docking time, console time, ureterovesical anastomosis time and estimated blood loss were 8 min, 92 min, 26 min and 200 mL, respectively [22]. There were three blood transfusion events - one intra-operatively due to a blood loss of 1 500 mL and two patients post-operatively. There were no other major complications. The median hospital stay was 4 days. At 3 months, four patients had positive surgical margins was observed in 4 patients, one patient had BCR, and 15 patients achieved continence.

In another institution, using the Da Vinci system, RARP was performed in 66 patients with prostate cancer [9]. Lymph node dissection was also performed in 35 patients, and 12 (18.2%) had positive lymph node disease. Median operative time was 210 minutes, console time was 130 minutes

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and estimated blood loss was 200ml. Median hospital stay was 7 days. Postoperatively, 23 patients (34.8%) had positive surgical margins.

4. Discussion and Limitations

As a whole, when compared to open or laparoscopic surgery, robotic-assisted surgery has shown benefits such as shorter length of stay, lesser blood loss and fewer complications, with specific benefits such as shorter WIT in renal surgeries [23, 24]. Comparing Hinotori to the pre-existing well-acclaimed Da Vinci system already on the robotic market, both perioperative and postoperative findings revealed favorable outcomes which were non-inferior to that of the Da Vinci. This reviewed parameters such as intraoperative time, EBL, perioperative events (transfusions, conversion to open surgery), length of hospital stay, as well as major postoperative complications. Considering these encouraging findings, Hinotori is very promising as a non-inferior option in comparison to the Da Vinci system, with favourable outcomes and similar safety profiles.

The benefits that the novel Hinotori system has to offer are largely advantageous, including increased flexibility of robotic arm movement with 8 axes of movement range which simultaneously inhibits interference between multiple robotic arms. This has specifically been designed to realize accurate and minute manipulations in each surgery. Other technical aspects such as software calibration of trocar position without docking arms results in the provision of a large space in a clean field and protects against collisions between arms outside the body. This, in conjunction with the flexibly positioned 3D viewer mounted in the surgeon's cockpit brings greatly desired convenience and reduces fatigue for the surgeon. Such benefits allow a great range of urological surgeries to be performed, showing extreme significance and importance in challenging, complex surgeries such as IVCTT. In terms of device error, device errors were detected in 4 of 30 (13.3%) surgeries, related to updating of the control programs [25]. Conversely, da Vinci reports device failure in 0.4%–0.5% of cases, with robotic surgeries converted to open [21, 26]. Hence, the device error rate and safety profile were similar.

Drawbacks of a new type of robotic-assisted surgery in urology include factors such as longer operating time as well as increased difficulty in training surgeons. Furthermore, the cost-effectiveness of the Hinotori system remains unstudied when compared to other robotic systems. It remains that current robotic systems are still experiencing cost concerns. However, if cost concerns are balanced against expansion of indications and superior outcomes, it may just tip the scale over. Another drawback highlighted in Motoyama's paper on RANU, mentioned that RANU could be completed without re-docking in the da Vinci but not using the Hinotori. This is particularly during movement from kidney to bladder direction to determine the trocar position by software-based calibration. The study acknowledged that this may contribute to differences in perioperative outcomes.

5. Conclusion

The rapid adoption of the Hinotori system since its induction in 2019 in Kobe, Japan, underscores its expansive potential in advancing minimally invasive urological surgeries. This innovative system offers substantial advantages in enhancing surgical precision and patient outcomes, positioning it as a strong contender in the field of precision-based surgery. Unsurprisingly, its success extended beyond Urology to other surgical specialties. Current literature supports its non-inferiority to the well-established Da Vinci system, with no major drawbacks or concerns identified. Future studies involving larger cohorts and more complex surgical cases are essential to further evaluate the efficacy and safety of the Hinotori system. Longer term data is required to evaluate prognostic outcomes and long-term outcomes. Such research will be crucial for establishing its role in the global landscape of urological surgery.

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