Robot-Assisted Surgeries: Developing a Database for Future Research on Better Practice

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Abstract

Although the first FDA approved utilization of Intuitive Surgical's da Vinci® Surgery System dates back to the year 2000, the Lehigh Valley Health Network (LVHN) only began using this emergent technology for minimally invasive surgery in 2007. Since the inception of the Robotic Surgery Department roughly 8 years ago, the LVHN has performed over 4,000 robotic cases—a number seemingly large enough to derive valuable insight into the clinical and economic effectiveness of robotic surgeries from retrospective analysis. The LVHN has a large repository of electronically stored patient records for each robotic case that can be transformed into an IRB-approved database, which can be designed with a simple interface that allows future data input and interpretation. This ongoing project included the compiling of the initial version of this database, which can be used at a later date after the database is deemed large enough and reviewed by NORI statisticians, to compare, both clinically and economically, robot-assisted surgery versus open and laparoscopic surgery at an institutional level. The findings can then be put to use in the form of quality/process improvement projects to streamline clinical efficacy and reduce hospital expenditures, or put to use by supporting other robotics-related research endeavors.

Background

The purpose of surgical robots is to assist in laparoscopic procedures or to be utilized in procedures never before possible with an open or laparoscopic technique. These robots were initially designed to be used for telesurgeries in which a physician could control the robot by console from a remote distance, but physicians helping with the design of the precursors realized their potential for assisting in difficult laparoscopic surgery (Lanfranco et al., 2004). In 1985, the first documented robot-assisted procedure transpired when the PUMA 560 was used to perform precise neurosurgical biopsies (Kwoh et al., 1988). More than a decade later a commercial venture, which was an offshoot of a project devised by the US Army to bring robotic surgery to the frontlines of war in an attempt to decrease mortality rates (Satava, 2002), licensed the SRI Green Telepresence Surgery System. This company, then called Integrated Surgical Systems, refined their technology and then produced what they renamed as the da Vinci® Surgical System (Lanfranco et al., 2004). Currently, the LVHN has 3 da Vinci® Si HD Surgical Systems, including 2 located at the Cedar Crest campus and 1 located at the Muhlenberg campus.

In 2011, the Canadian Agency for Drugs and Technologies in Health (CADTH) published a report documenting their systematic review and meta-analysis of the clinical efficacy and cost-effectiveness of robotic surgery in Canadian, American, and European health service centers compared to open and laparoscopic surgery offered by the same providers. This study focused solely on four procedures—prostatectomy, hysterectomy, nephrectomy, and cardiac surgery—and there was only limited data for nephrectomy and cardiac surgery. This review included many subgroup analyses, but overall, robot-assisted surgery showed statistically significant benefit to clinical outcomes. These outcomes included reduced length of stay for patients undergoing all four surgery types, reduced blood loss and transfusion rates for all four surgery types, and reduced post-operative complications with robot-assisted hysterectomies compared with open and laparoscopic hysterectomies. In terms of cost-effectiveness, since the expense associated with purchasing and maintaining robot surgical robots is so steep, it was determined that surgical caseloads would need to increase to lower the incremental cost per patient associated with robotic surgeries in order to make them more economically viable (Ho et al., 2011).

At the present, the LVHN only has an initial precursor to what will become an institution-wide IRB-approved database documenting the data for each case in Department of Robotic Surgery starting after June 1, 2008. This data is scattered within thousands of pages of electronic medical records stored in the soon-to-be defunct Centricity EMR database. The long-term goal of this project is to neatly compile all relevant data in a microcomputer database so that is can easily be statistically analyzed, similar to CADTH's analysis of surgical data from multiple institutions, by a trained statistician from NORI within the LVHN. Retrospective analysis of the database could then help shape the future of the Department of Robotic Surgery with a focus on quality improvement of a clinical and economic nature within the LVHN, and other research comparing robotic, open, and laparoscopic surgery within or outside of this institution.

Methodology and Results

Before the beginning of the Research Scholars Program this summer, the Department of Robotic Surgery at the LVHN had already created a password-protected database in Microsoft (MS) Access to store data as part of clinical practice. Along with the database, specially designed forms were constructed that allow for user friendly data-entry (Figure 1). These forms were divided into five subsets, separated on the navigations page (Figure 2), which reflect the type of surgery each case falls under—general (~150 cases), colorectal (~50 cases), gynecological (~775 cases), cardio-thoracic (~120 cases), or urological (~12 cases). The number of cases for each subset is not exact because discrete cases are continuously being added to the database, seeing as this project is only at its initial stage. As a new robotic case is added, it is designated its own form, and when data is entered into the form it is automatically captured in the master table as well. Initially, each form contained the patient's full name, account number, and date of surgery, but most of the essential information had not been entered yet. Some data, such as procedural costs and readmission data, can automatically be pulled from existing LVHN databases, but this only occurs biannually thus making the constant development of this robotic surgery database necessary in order for retrospective analysis to ever occur.

After obtaining IRB approval to build a new database, the existing MS Access database was developed by manually entering data found within electronic medical records stored in the Centricity EMR application. Table 1 displays the comprehensive list of all data points which populate the new database. The data were entered either as a textual description (i.e. Procedure), a discrete number (i.e. BMI), a number within a given range to differentiate between severity (i.e. PostOp Complication), or as a dichotomous true or false statement (i.e. Comorbidities). The object-oriented forms contain drop-boxes which catalog data that is commonly repeated in multiple cases. Any data point that repeats itself in more than one case was added to its respective drop-box to ensure that identical data entries are always characteristically entered in the same format.

To make the database user-friendly, the forms in the MS Access application will perpetually be used so that anyone who continues the development of the robotic surgery database will not disrupt its standardization. But consultation with NORI made it clear that the new IRB-approved database should exist within a MS Excel workbook for easier statistical analysis. Therefore a macro (Figure 3) was programmed using Visual Basic for Applications (VBA), which automates the exportation of the master table in MS Access into an IRB-approved database in MS Excel, saved on the LVHN X drive. Any time the macro is run, the new robotic surgery database in MS Excel will update to reflect any changes made in the joint MS Access database.

Discussion

The goal of this project is to eventually conduct research using the new robotic surgery database in MS Excel. Before conducting research or quality/process improvement projects, IRB approval must be obtained specifically for the design of these theoretical projects, since IRB approval has only been granted for the creation of the robotic surgery database thus far. Albeit, at this point in time it is clear that more cases need to be conducted before any statistically supported conclusions can be derived from the data. Table 2 lists all of the types of procedures that have been performed in the Department of Robotic Surgery to date. Robot-assisted, open, and laparoscopic outcomes can only be compared for the same type of procedure, or else variability would be introduced. Therefore, even though the Department of Robotic Surgery at the LVHN has performed thousands of procedures, the numbers of cases for individual procedures are a lot lower than the sum of them all. There would also be other confounding variables such as the physician's experience or complications with the surgical robot, so, once again, more cases are needed.

In the future, when there is sufficient data, this database could be used to compare continuous data such as the length of stay or time in the operating room. This data can be expressed as weighted mean differences, and then it could give insight into whether or not robotic-assisted surgeries do reduce recovery times, due to their minimally invasive nature. Shorter surgeries would also mean that the hospital could take on heavier caseloads that would help offset the exorbitant cost of the da Vinci® Surgery Systems. Complication and readmission rates could be expressed as risk ratios. If robot-assisted procedures have a lower risk of complication or patient readmission within 30 days, the use surgical robots may help reduce extra health care related expenditures, which is positive from a societal perspective. Research on the cost-effectiveness of the robotic surgeries could help determine whether or not it would be practical to expand the Robotic Surgery Department. Expansion would be benefitted by the prospective reduced cost of the robotic systems, which is believed to occur as the technology advances and as physicians become more experienced with robotic procedures (Kim et al., 2002).

Looking forward, this database could be expanded to include positive margin occurrences at different stages of cancer for oncological cases. In the meta-analysis performed by the CADTH, positive margin rates were found to be heavily reduced in robot-assisted prostatectomy cases compared to laparoscopic and open prostatectomy cases at the pT2 stage (Ho et al., 2011). Therefore, if retrospective analysis finds that robotic-assisted surgery reduces positive margin rates in clinical cancer cases across the board within the LVHN, then cancer recurrence in LVHN patients could drop off and this health network will have better outcomes in surgical oncology procedures. Ultimately, this database could have a large positive impact on society and on the hospital, which is why it is exigent that this database be continually developed as surgical robots become the norm in hospitals everywhere.

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Appendix

Figure 1. Blank data form from the robotic surgery MS Access database.

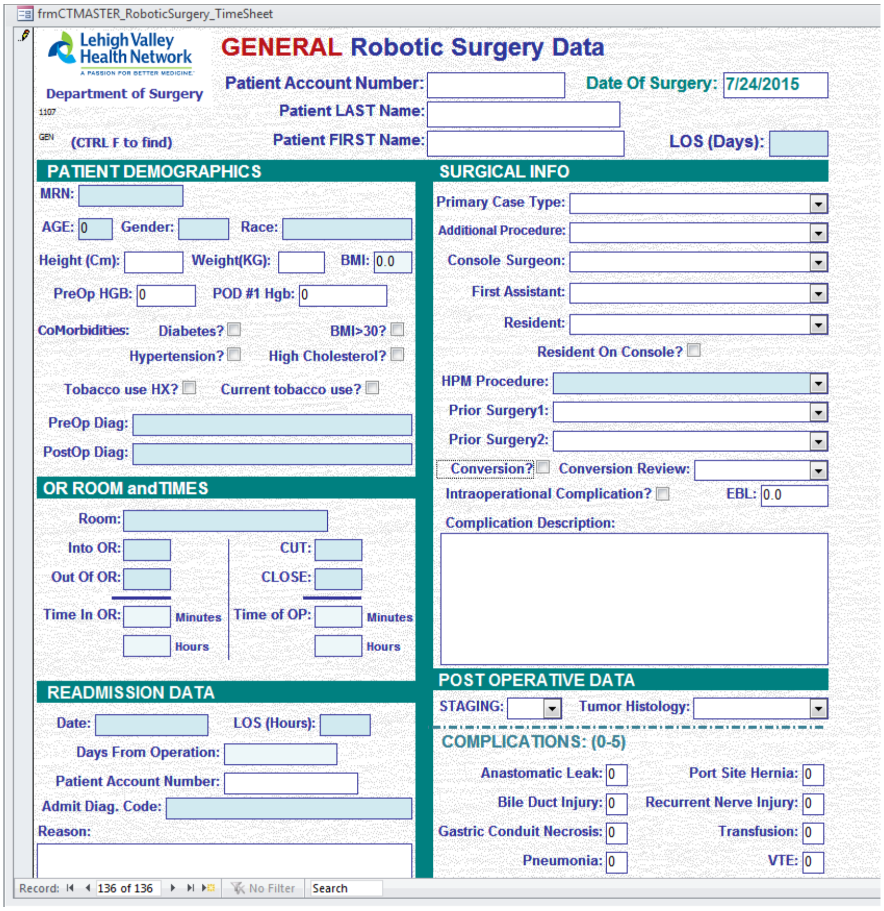

Figure 2. Navigation page within robotic surgery MS Access database

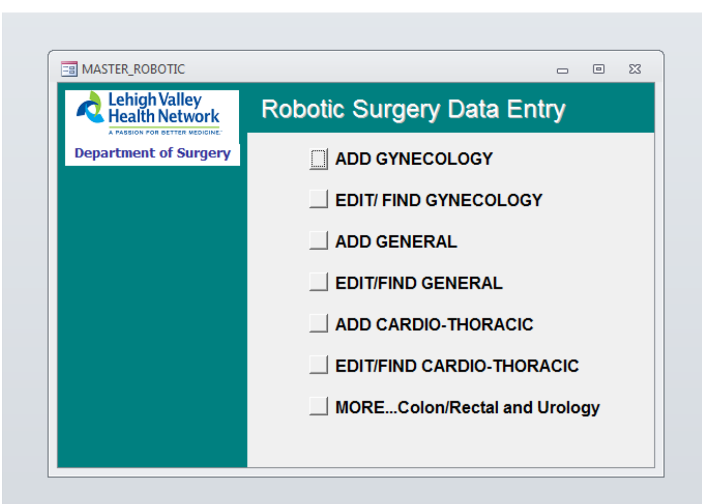

Table 1. Comprehensive list of data stored within the new IRB-approved MS Excel database

Patient Demographics	**Comorbidities**	**Surgical Info**	**OR Info**	**PostOp Data**	**Readmission Data**
Patient Name	BMI > 30?	PreOp Diagnosis	Room	Cancer Staging	Date
Patient Account #	Diabetes	PostOp Diagnosis	Into OR (time of day)	Tumor Histology	Length of Stay (hr)
MRN	Hypertension	Primary Case Type	Out of OR (time of day)	Anastomatic Leak (0-5)	# Days from Op
Gender	High Cholesterol	Additional Procedure	Time in OR (Hr and Min)	Bile Duct Injury (0-5)	Patient Account #
Race	Tobacco Use HX?	Console Surgeon	Cut (time of day)	Gastric Conduit Necrosis (0-5)	Admit. Diag. Code
Height (cm)	Current Tobacco Use?	First Assistant	Close (time of day)	Pneumonia (0-5)	Reason for Readmission
Weight (kg)		Second Assistant	Time of Op (Hr and Min)	Port Site Hernia (0-5)	
BMI		Resident on Console?		Recurrent Nerve Injury (0-5)	
PreOp HGB		Conversion?		Transfusion (0-5)	
PostOp HGB		Conversion Review		Venous Thromboembolism (0-5)	
Date of Surgery		HPM Procedure Code		Blood Clot (0-5)	
Length of Stay (Days)		Prior Surgery 1		Other Complication	
		Prior Surgery 2		Other Complication Description	
		EBL (cc)		Discharged with Foley?	
		Intraoperational Complication		Discharge with Chest Tube?	
		Complication Description		Discharged with Drain?	
		Uterine Wt (g)		# of Lymph Nodes Removed	
		Suture Type		Discharge Disposition	
		Chest Tube Size			

```
'------------------------------------------------------------
' Export_To_Excel
'
'------------------------------------------------------------
Function Export_To_Excel()
On Error GoTo Export_To_Excel_Err

    Beep
    MsgBox "File will be exported to IRB approved database in Excel", vbCritical, ""
    DoCmd.OutputTo acOutputTable, "tblMASTER_RoboticSurgery", "ExcelWorkbook(*.xlsx)", "X:\Robotic Surgery Program\Robotic Surgery Program\Dep. of Robotic Surgery Database.xlsx", True, "", , acExportQualityPrint


Export_To_Excel_Exit:
    Exit Function

Export_To_Excel_Err:
    MsgBox Error$
    Resume Export_To_Excel_Exit

End Function
```

Figure 3. VBA macro script for exportation of data to MS Excel database

Table 2. Comprehensive list of surgeries performed by the LVHN Department of Robotic Surgery to date

Gynecology	**General**	**Cardio-Thoracic**	**Colon/Rectal**	**Urology**
RATLH	Distal Pancreatectomy	3F Esophagectomy	Abdominal Perineal Resection	Left Radical Nephrectomy
RATHL BSO	Heller Myotomy	IL Esophagectomy	Lower Anterior Resection	Right Radical Nephrectomy
Bilateral Salpingo-Oophorectomy	Incisional Hernia	Mediastinal LND	Left Colectomy	Partial Nephrectomy
Cystectomy	Ventral Hernia	Heller Myotomy	Right Colectomy	Robot-Assisted Radical Prostatectomy
Excision of Endometriosis	Right Hepatectomy	Lobectomy	Rectopexy	
Lysis of Adhesions	Left Hepatectomy	Pleurectomy	Sigmoidectomy	
Laparoscopic Salpingo-Oophorectomy	Liver Wedge	Segmentectomy		
Myomectomy	Multiport Cholecystectomy	Thymectomy		
Radical Hysterectomy	RSS cholecystectomy	Wedge Resection		
Trachelectomy	Paraesophogeal			
Right Salpingo-Oophorectomy	Nissen fundo			
RSS TLH	Partial Gastrectomy			
Sacrocolpopexy	Peritoneal Biopsy			
	Sleeve Gastrectomy			