

The Utilization of Splenectomy Post-Op Clinical Vaccinations Order Set to Enhance Adherence and Timeliness of Vaccinations in Emergency Splenectomy Patients: A Pre-and-Post Intervention Study

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Conflict-of-interest statement: The authors declare that there is no conflict of interest regarding the publication of this paper.

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Received: July 29, 2020

Revised: December 1, 2020

Accepted: December 4, 2020

Published online: February 21, 2021

ABSTRACT

BACKGROUND: Asplenic patients are at increased risk of serious and life-threatening infections, especially by encapsulated pathogens. These infections are easily prevented with appropriate vaccinations post-splenectomy. The Splenectomy Post-Op Clinical Vaccinations Order Set is one of the first initiatives to harmonized practice between sites at our organization.

OBJECTIVES: This is a pre and post-intervention study aimed to assess the impact of the Splenectomy Order Set to improve practice adherence to recommended vaccination protocols outlined by the Canadian Immunization Guidelines among patients undergoing emergency splenectomy.

METHODS: A 5-year retrospective chart review was conducted in 2013 for the pre-intervention vaccination rates. Another 5-year retrospective chart review was conducted in 2018 to determine post-intervention rates. The quantitative results were then tallied and analyzed.

RESULTS: Overall, 46 patients were included in the pre-intervention group and 40 patients in the post-intervention group. Prior to the implementation of the Splenectomy Post-Op Clinical Vaccinations Order Set, 61% of patients at the organization received the required vaccinations. Post-intervention, vaccination rates increased to 93%. There is a statistically significant difference between the two groups with a p value less than 0.01. Similarly, in terms of appropriate timing, pre-intervention, 48% of patients received the vaccines in the right timeframe and post-intervention, this rate increased to 80%. This difference did not reach statistical significance due to a smaller sample size.

CONCLUSION: This quality improvement study showed that a multidisciplinary and evidence-based order set can significantly improve appropriate drug prescribing and patient care while sustaining improved outcomes.

Key words: Splenectomy; Vaccinations; Prophylaxis; Adherence; Guidelines

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Liao X, Sengar A. The Utilization of Splenectomy Post-Op Clinical Vaccinations Order Set to Enhance Adherence and Timeliness of Vaccinations in Emergency Splenectomy Patients: A Pre-and-Post Intervention Study. *Journal of Gastroenterology and Hepatology Research* 2021; **10(1)**: 3411-3416 Available from: URL: <http://www.ghrnet.org/index.php/joghr/article/view/3095>

ABBREVIATIONS: overwhelming post-splenectomy infections (OPSI), Trillium Health Partners (THP), Mississauga Hospital (MH), Credit Valley Hospital (CVH), general practitioners (GP), United States of America (US), United Kingdom (UK).

INTRODUCTION

The spleen is a hematopoietic organ that participates in cellular and humoral immunity, as well as in the removal of senescent red blood cells, bacteria, and other foreign particles from the body's circulation^[1]. The removal of the spleen (splenectomy) is indicated for a variety of diseases and conditions, such as sickle cell anemia, thalassemia major, essential thrombocytopenia, celiac disease, inflammatory bowel disease, certain types of cancer, and trauma^[2]. Asplenic patients are at increased risk of serious and life-threatening infections, termed overwhelming post splenectomy infections (OPSI), with a lifetime risk of 5%. These infections are associated with a high mortality rate at 50-80% as OPSI causes rapid deterioration in the susceptible patient^[3]. Of concern are encapsulated pathogens (*Streptococcus pneumoniae*, *Haemophilus influenzae* type b [Hib], *Neisseria meningitidis*) which can cause fulminant sepsis and other difficult-to-treat infections^[1]. OPSI can be prevented if protective measures such as timely vaccinations, prescription of antibiotics for fever, and physician and patient education are implemented^[7].

Several organizations worldwide have developed guidelines outlining strategies to prevent OPSI. Evidence supporting the recommendations is mostly based on clinical studies (retrospective studies and case reports) and expert opinions^[8,9,10]. Large prospective studies are not available as the incidence of OPSI is relatively rare and the patient population is small^[7]. In the Canadian Guidelines for Immunization of Immunocompromised Persons, it is recommended that asplenic patients receive prophylactic immunizations and yearly influenza vaccinations to protect against post-splenectomy infectious complications. For elective surgical splenectomies, vaccines should be administered at least 2 weeks before the procedure. For emergency splenectomies, vaccines should be given 2 weeks after the procedure. If the patient is discharged earlier than 2 weeks and there is difficulty to follow-up with them, vaccination should be administered before discharge^[2]. In the British Guidelines for the Prevention and Treatment of Infections in Patients with an Absent or Dysfunctional Spleen, antibiotic prophylaxis, as well as patient and physician education are also recommended^[8].

In terms of vaccine efficacy, the pneumococcal polysaccharide 23-valent vaccine was introduced in the 1970s, which includes 23 bacterial serotypes responsible for about 88% of pneumococcal infections. However, reports in the literature indicate that the vaccine efficacy is poor in younger patients, especially in children. In addition, the most virulent serotypes are the least immunogenic and approximately 10% of possible antibody response to antigens does not develop^[8]. Thus, there is a risk of prophylaxis failure with the polysaccharide vaccine and some experts recommend the addition of the pneumococcal conjugate 13-valent vaccine to improve antibody response and immunologic memory. The conjugate vaccine should be given 8 weeks before the polysaccharide vaccine. However, the polysaccharide vaccine is still the vaccine of choice in asplenic patients and if only one can be administered, this one is preferred^[2]. The meningococcal and haemophilus influenzae type b vaccines, on the other hand, are both highly efficacious against the serotypes covered. Revaccination every 5 years is recommended in high risk patients to maintain antibody concentrations with the pneumococcal and meningococcal vaccines, but not necessary with the haemophilus influenzae type b vaccine as almost all adults are sufficiently immunized against

this serotype in childhood^[9].

Ideally, all vaccines should be given at least 2 weeks before splenectomy as this confers protection against infections before the procedure^[10]. However, in the case of emergency splenectomy, the timing of vaccine delivery recommendations is based on a study that administered the pneumococcal vaccine at 1, 7, or 14 days after splenectomy in 59 trauma patients who received emergency splenectomy compared to 12 adult controls. Post-vaccination antibody concentrations were not significantly different between groups. However, post-vaccination antibody activity was significantly reduced in the early vaccination groups (days 1 and 7)^[4]. Although there are several limitations in this study in that the investigators only looked at trauma patients, the control group may be different from the study group as trauma can affect the patients' ability to mount an antibody response, and the decrease in antibody response could be related to the time from traumatic episode, similar studies shown variable results and this study has been the most commonly cited in the guidelines. Therefore, the guidelines recommend delayed administration of vaccination. If this is not possible, or the patient cannot or is unlikely to come back for a follow-up appointment, then early administration of vaccination is recommended over vaccination omission^[2].

The following Canadian immunization schedule is recommended for asplenic patients:

1. Meningococcal disease: (1) Two doses of Men-C-ACYW-135 vaccine are recommended for persons with asplenia. When elective splenectomy is planned, all recommended vaccines should ideally be completed at least 2 weeks before surgery; if only one dose can be given before surgery, the second dose should be given 8 weeks after the first dose (with a minimum interval of 4 weeks). In the case of an emergency splenectomy, two doses of vaccine should ideally be given beginning 2 weeks after surgery but can be given earlier, before discharge, if the person might not return for vaccination after discharge. Note that persons one year of age and older with asplenia who have not received Men-C-ACYW-135 vaccine should receive two doses administered 8 weeks apart (with a minimum interval of 4 weeks). (2) A booster dose of Men-P-ACYW is recommended every 5 years in adults. (3) A new vaccine, Bexsero, which covers Meningococcal group B, was newly recommend in May 2018. The vaccine will not be studied as it is a new recommendation.

2. Pneumococcal disease: (1) Adults who have not previously received pneumococcal vaccines should be vaccinated with Pneu-P-23. When circumstances permit, some experts suggest that the conjugate vaccine (Pneumococcal Conjugate 13-valent) may be given as the initial dose followed by the polysaccharide vaccine (Pneumococcal Polysaccharide 23-valent) 8 weeks later, as this may theoretically improve antibody response and immunologic memory. However, the polysaccharide vaccine is the vaccine of choice for these individuals, and if only one vaccine can be provided it should be the polysaccharide vaccine. (2) A single booster with Pneu-P-23 is recommended after 5 years in those aged greater than 10 years at the time of initial immunization.

3. Haemophilus influenzae type b: (1) Despite limited efficacy data and the low overall risk of Hib sepsis in individuals greater than 5 years of age, especially in the era of high Hib immunization coverage in the population, some experts recommend that all asplenic individuals greater than 5 years of age receive a single dose of conjugate Hib vaccine, regardless of previous Hib immunization. (2) No booster is necessary.

The recommendations regarding the administration of prophylactic antibiotics have been variable in the guidelines worldwide. Robust evidence in this area is lacking and data is mainly based on small observational studies and expert opinions. The most recent British guidelines (2011) recommend continuous and lifelong antibiotic prophylaxis or prophylaxis for at least the first two years after splenectomy, with oral penicillin V or macrolides. In case of suspected or proven infection, patients should be given empiric antibiotics immediately and be admitted to a hospital^[13]. However, the issue of antibiotic prophylaxis is controversial. Most studies show that adherence rate to the British guidelines is low due to several reasons: there is a lack of proven clinical efficacy and a risk of increasing penicillin resistance. In addition, lifelong compliance may not be achievable in most patients. Therefore, another option is to have an “emergency supply” of antibiotics to take at the first sign of infection e.g. fever, which is the recommended approach at Trillium Health Partners (THP)^[10].

The guidelines also recommend patient and physician education with written information and cards to alert healthcare professionals^[2]. Previous studies have reported that up to 60% to 70% of all asplenic patients have limited or no knowledge about their infection risk. This is especially true in trauma patients, who underwent emergent surgery and did not receive pre-operative education. In addition, these patients may not be able to fully comprehend the risks associated with splenectomy after surgery as they may be in acute stress and/or sedated with analgesics. Furthermore, most patients are managed in the hospital for only a short period of time and are followed-up by general practitioners (GPs) in the community. Thus, there is a limited timeframe in which these patients could be educated^[15]. Ideally, patients, their caregivers, and all healthcare professionals should be educated on the risk of OPSI in asplenic patients. These patients should be encouraged adhere to preventative measures before discharge as they confer a high level of protection when followed correctly^[5]. In addition, GPs should be informed of the need for scheduled booster vaccinations and follow-up with their patients accordingly.

RATIONALE FOR RESEARCH STUDY

Although several guidelines and studies from Canada, United States, and Europe have been published on the topic, the literature suggests that the incidence of OPSI has remained constant over time^[6,12]. Also, reports from the 1990s to the present have shown that compliance rates to guidelines vary considerably, ranging from 60-91%. Most studies report suboptimal uptake and implementation to the outlined preventive measures^[13]. Moreover, most of the research on this topic is done in Europe.

The Splenectomy Order Sets (pre-op for scheduled and post-op for emergency), developed by Trillium Health Partners, allow clinicians to administer the recommended vaccinations in a timely manner, prescribe empiric antibiotic therapy in case of fever, speak to patients about MedicAlert bracelets, and book hospital outpatient Infectious Disease clinic appointments so that patients receive their vaccinations within the recommended timeframe if they are discharged early (Appendix 1). Also attached to the Order Sets are standardized information sheets for patients and their GPs (Appendix 2 and 3, respectively). Therefore, this project offers a unique interventional strategy to ensure every patient who undergoes splenectomy at Trillium Health Partners receives the correct vaccinations in the appropriate timeframe, antibiotic prophylaxis (if required), education regarding their condition, and the opportunity to be followed-up with healthcare providers appropriately at hospital outpatient clinics and GP offices.

The aim of this project is to investigate the effectiveness of using Splenectomy Order Sets in a large community hospital in Missis-

sauga, Ontario, Canada to increase the timely adherence to recommended vaccination protocols outlined by the Canadian Immunization Guidelines among patients undergoing emergency splenectomy.

RESEARCH QUESTIONS

What is the rate of adherence to the vaccination recommendations made by the Canadian Immunization Guidelines in patients undergoing emergency splenectomy before and after the implementation of Splenectomy Order Sets?

In patients who received emergency splenectomies, is the timing of vaccination administration in accordance to the Canadian Immunization Guidelines before and after the implementation of Splenectomy Order Sets?

METHODS

Project Design

The questions will be addressed using a retrospective pre-and-post intervention study design. The intervention is the implementation of Splenectomy Order Sets, which was launched in August 2013 at Trillium Health Partners. For patients who meet the study inclusion criteria, minimal data regarding baseline characteristics will be collected. Table 1 lists the variables for which data will be collected for each eligible patient.

Patient Population

Table 1 Variables for which data will be collected for each patient

Variable
Patient demographics
Age at splenectomy (years)
Sex (n, % of M/F)
Year of operation
Indication for splenectomy

Inclusion Criteria: (1) Patients equal to or greater than 18 years old (adults); (2) Patients admitted to Trillium Health Partners (Mississauga Hospital and Credit Valley Hospital) for emergency splenectomy between January 1st, 2008 to December 31st, 2012 (pre-intervention) and August 1st, 2013 to August 31st 2018 (post-intervention).

Exclusion Criteria: (1) Patients who received partial splenectomy; (2) Death during or within the first 72 hours following splenectomy; (3) Patients who have contraindications to receiving vaccinations.

Procedure

Adult patients who were admitted for emergency splenectomy at Trillium Health Partners from January 1st, 2008 to December 31st, 2012 will be eligible for inclusion into the pre-intervention component and from August 1st, 2013 to August 31st, 2018 will be eligible for inclusion into the post-intervention component. The timeframe was chosen to start from 2008 as the Canadian Immunization Guidelines were revised in July 2007. The pharmacy department has been tracking the uptake of vaccines in splenectomy patients as part of a standard quality assurance process prior to the implementation of the order sets. A 5-year pre and post design was determined to be the study timeframe due to the small number of patients annually undergoing this procedure. This timeframe will ensure surgeons have had sufficient time to familiarize themselves with the order set, and to show a sustained practice.

Study Definitions

Vaccination is appropriate if all three immunizations (pneumococcal, meningococcal and haemophilus influenzae type b) were given.

Scheduled splenectomies include procedures which were planned between the patient and the healthcare provider.

Emergency splenectomies include procedures which were not planned, such as emergency situations such as spleen rupture due to trauma. Emergency splenectomies also include cases in which during the operation it was decided to remove the spleen and inadvertent splenectomies.

Timing is considered to be appropriate if: For emergency splenectomies, the vaccines were administered 12-16 days after the operation or were administered before discharge.

PROJECT OBJECTIVES

Primary Objective: To determine the proportion (n, %) of patients who received all three vaccinations (pneumococcal, meningococcal and haemophilus influenzae type b) before and after the implementation of Splenectomy Order Sets.

Secondary Objective: In patients who received all three vaccinations, to determine the proportion (n, %) of patients who received the vaccinations within the appropriate timeframe.

STATISTICAL ANALYSIS

Categorical variables will be expressed as proportions, and continuous variables as means (\pm standard deviation). Data from categorical outcome measures will be compared using the Fisher exact test (sample size < 100) or chi-square test (sample size > 100). Continuous data will be compared using the student t-test. All tests of significance will be two-tailed, and a p-value of ≤ 0.05 will be considered statistically significant.

In terms of sample size requirement, assuming a target of 90% compliance rate in the post-intervention period, we will need 40 patients in each group (80 patients in total).

RESULTS

Overall, 495 patient charts were reviewed and 409 were excluded. The most common cause of exclusions was elective splenectomy or other surgical processes. 46 patients were included in the pre-intervention group and 40 in the post-intervention group, which meets the required power of this study to achieve statistical significance.

In terms of baseline characteristics, the median age of patients was 60 years old. 47% of the patient population was female. The most common indication for emergency splenectomy was removal during intraoperative procedures.

In the pre-intervention group, 61% of patients at THP received the appropriate vaccinations. In the post-intervention group, the rate increased to 93%. There is a significant difference between the two groups with a p value less than 0.01.

Similarly, in terms of appropriate timing, 48% of patients received the vaccines in the right timeframe in the pre-intervention group, and post-intervention, this increased to 80%. This difference did not reach significance due to a smaller sample size. Most patients received the vaccines within 5 to 20 days post-op or prior to discharge.

DISCUSSION

The Splenectomy order set is a multi-disciplinary and evidence-based protocol to ultimately increase vaccination rates in asplenic patients and prevent catastrophic infections and unnecessary hospital admissions. OPSI is a preventable condition using several guideline-recommended vaccines administered to splenectomy patients both before and after the removal of the spleen. This protocol contains the recommended vaccinations, ideal timing, and reminders for follow

up to prescribers to sign-off post-operatively. In-depth patient counselling sessions are provided by a pharmacist or nurse at the bedside, prior to discharge. Patient information pamphlets are also included, in addition to letters for family physicians for seamless care.

A five-year retrospective review of adherence to splenectomy guidelines was done by Kotsanas et al. in an Australian hospital from 1999-2004 published in 2006. This study included 111 patients who have undergone splenectomy. The results of the study show that education for prevention of sepsis is vitally important. Women were four times more likely to receive education about vaccine prophylaxis than men ($p = 0.028$) and older patients were 28% less likely to receive education ($p = 0.009$) than younger patients. However, the study author found that their centre's vaccination rates dramatically improved after the implementation of protocols and guidelines. Vaccination education rates in 2004 were 22 times higher than those in 1999. The results indicate that improved patient education, particularly targeting male patients and older patients, is an important factor in improving vaccination rates^[16].

In the United Kingdom (UK), several studies looked at vaccination rates in asplenic patients. Of note, a study by Siriwardena et al. in 2003 implemented multi-disciplinary protocols and guidelines to increase vaccination rates and found that vaccination rates improved by 17.3% post-interventions^[17]. More recently in 2017, a five-year retrospective review conducted in the UK was published by Boam et al. This study aimed to look at vaccination adherence rates after a national guideline was published in 2006. The investigators implemented protocols in two teaching hospitals to increase vaccination rates through patient and clinician education. Approximately ninety one percent of the 100 enrolled patients received the appropriate triple vaccines peri-operatively. Eighty-six percent received post-operative antibiotics^[18]. This is a significant improvement from the previous UK studies on vaccine rates and demonstrates that a multi-disciplinary approach and standardized protocols can have an immensely positive impact on patient care.

A more proactive study conducted by Hans et al. in 2005 studied patients who had undergone splenectomy in the United States (US). They developed guidelines, provided educational sessions and emails, conducted patient outreach such as phone calls, and provided counselling and information leaflets before assessing the vaccination rates. Prior to their interventions, only 2.7% of patients were up to date on their vaccinations. After clinical education, 20% of all patients received vaccinations. After patient outreach initiatives, this rate increased to 82.7%^[19]. This highlights the importance of patient education in association with vaccination rates. A more recent study published in 2017 by Carrico et al. assessed patient knowledge of sepsis risk and only 46% were aware of vaccination requirements^[20]. This demonstrates that patient education is an important requirement in recent times to improve vaccination rates.

Another study in the US assessed the effectiveness of patient education on vaccination rates between 1996-2011. One hundred and forty-four splenectomy patients were studied, and the mean follow up time compared to other studies. Only 27% of patients recall receiving education about vaccinations. Most patients thought their education was poor or minimal and 91% of them wanted more information via reading material. Subsequently, however, the hospital improved their guidelines and protocols for education. Between 2008-2011, 100% patients received all three recommended vaccines, and revaccination rates were 39% and 15% for *S. pneumoniae* and *N. meningitidis* vaccines, respectively^[21]. This study once again demonstrates that it is possible to significantly improve vaccination rates by effectively

implementing multi-disciplinary education and protocols.

Meier-Stephenson *et al.* in 2014 conducted a similar pre and post study in Alberta, Canada. A peri-splenectomy vaccination kit dispensed through pharmacy included standardized orders, all vaccines, patient and family physician information letters and a patient card that documented the vaccinations received. The vaccination rates between 2004-2006 prior to the intervention were overall 78%, post-intervention was overall 96%^[22]. This pharmacy driven initiative successfully increased vaccination rates.

Similar to the studies reviewed, THP has significantly improved our vaccination rates by 32% over the past 5 years. It also improved access as inpatient vaccinations prior to discharge ensures that asplenic patients would not be missed and must otherwise procure expensive vaccines in the community. Lastly, the order set sustained the improved vaccination rates over the last 5 years. The order set, which included evidence-based recommendations and patient education was able to improve quality of patient care overall and contribute to better health outcomes. Prevention of OPSI also averts the associated patient hospitalization and mortality risk.

LIMITATIONS

Due to the retrospective nature of this project, it will be difficult to control for confounders and bias. Also, data will be retrospectively collected from a pharmacy quality assurance database, therefore missing or inaccurate data will limit the results of this review. Due to rarity of emergency splenectomy, the sample size is small.

In addition, the study of the other components of the Splenectomy Order Sets such as the effectiveness of patient and physician education and the pre-booking of follow-up appointments are not going to be studied individually, but it is theorized that these interventions would contribute to the increase in vaccination rates as a whole.

This project is also not investigating scheduled splenectomies and influenza vaccinations. At Trillium Health Partners, the majority of patients undergo emergency splenectomies. In addition, scheduled splenectomy patients tend to get their vaccinations as an outpatient weeks before the procedure, which is difficult to track in the hospital setting. Influenza vaccinations are not included due the same reason: many patients may get these vaccines in the community before or after the procedure and it is not feasible to collect this information. Also, influenza vaccination administration is highly time dependent.

CONCLUSION

In conclusion, OPSI can cause serious and life-threatening infections in asplenic patients and is associated with a high mortality rate. OPSI can be easily prevented with the use of appropriate vaccinations. Many studies around the world report low uptake on guideline recommendations and low vaccination rates overall. Patients often find that they do not receive adequate education on their infection risk. Physicians also report a need to change practice and increase communication amongst care providers.

Various strategies have been proven to increase vaccination rates for splenectomy patients. It was determined that a hospital protocol would be the most appropriate avenue to bring about changes. This quality improvement study showed that a multidisciplinary and evidence-based order set can significantly improve appropriate drug prescribing and patient care while sustaining improved outcomes.

ACKNOWLEDGMENTS

The study authors would like to acknowledge the contribution of Dr. Christopher Graham (infectious diseases physician), Tania Fernandes

(infectious diseases pharmacist), Anna Chiu (infectious diseases pharmacist), Joanne Stockford (infectious diseases pharmacist) and Neema Kapadia (surgery pharmacist) for their work on the development and implementation of the Splenectomy order sets are Trillium Health Partners.

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