Management of Uncomplicated Acute Appendicitis as Day Case Surgery: Can Outcomes of a Prospective Study Be Reproduced in Real Life?

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BACKGROUND: The feasibility of day case surgery (DCS) appendectomy for uncomplicated acute appendicitis (UCAA) was evaluated by the prospective AppendAmbu (Feasibility of Outpatient Appendectomy for Acute Appendicitis) study (ClinicalTrials.gov ID NCT01839435). The aim of this study was to evaluate the real-life feasibility of DCS for UCAA.

STUDY DESIGN: This single-center, retrospective, non-interventional study was conducted after the AppendAmbu study and included UCAA only. The primary end point was DCS success rate (ie length of stay <12 hours) in the intention-to-treat population (all patients with UCAA) and in the per-protocol population (population with UCAA and no preoperative and intraoperative exclusion criteria). The secondary end points were to determine the DCS quality criteria to evaluate and compare the morbidity and mortality of DCS and conventional hospitalization for UCAA (Clavien, Comprehensive Complication Index) and to externally validate the St Antoine criteria for the selection of patients for DCS.

RESULTS: From January 2016 to September 2017, two hundred and ninety-six patients underwent operations for acute appendicitis. The proportion of patients with successful DCS management was 27% in the intention-to-treat population and 95% in the per-protocol population. The unplanned consultation rate was 15%, the unplanned hospitalization rate was 4%, and the unplanned reoperation rate was 0%. The postoperative morbidity of patients managed by DCS was not different from that of patients managed in conventional hospitalization. The DCS success rate was 0%, with a St Antoine score of 0, and 80% of patients had a St Antoine score of 5 (p < 0.0001).

CONCLUSIONS: Day case surgery constitutes progress in surgery as a result of enhanced recovery programs. It avoids unnecessary prolonged hospitalization. (J Am Coll Surg 2019;229:277–285. © 2019 Published by Elsevier Inc. on behalf of the American College of Surgeons.)

Acute appendicitis (AA) is currently one of the most common digestive emergencies, and appendectomy remains the reference treatment for AA.[1,2] Uncomplicated AA (UCAA) is a disease of young people in good general condition, treated by appendectomy, mostly performed by laparoscopy, with a short hospital stay and few postoperative complications. Uncomplicated AA can therefore be a good indication for day case surgery (DCS). The feasibility of a length of stay <24 hours has been evaluated in several previous studies[3-6] and a review of the literature[7] and DCS, which corresponds to a length of stay <12 hours without overnight hospitalization, has also been

validated recently.[5,8-11] The AppendAmbu (Feasibility of Outpatient Appendectomy for Acute Appendicitis) study (NCT01839435) was the only study on DCS (together with the study by Lefrancois and colleagues[10]) based on a prospective cohort, with intention-to-treat (ITT) analysis. This methodology is the best available to evaluate the feasibility of DCS, but might induce a bias, as the protocol could artificially increase the DCS rate and might not accurately reflect the situation in clinical practice.

The aim of this non-interventional study was to evaluate the real-life feasibility of DCS for UCAA.

METHODS
Study design
This study (AppendAmbu II) was a single-center, retrospective, non-interventional study performed during a period after the single-center, prospective, descriptive, non-randomized, cohort, and ITT AppendAmbu study (ClinicalTrials.gov ID NCT01839435).

Inclusion and exclusion criteria
The inclusion and exclusion criteria were the same as those of the AppendAmbu study.[11]

Preoperative inclusion criteria were the following:

Related to AA: UCAA diagnosed on the basis of clinical, laboratory, and imaging criteria (CT scan or ultrasound).

Related to DCS: American Society Anesthesiology score <3, patient with sufficient understanding and good compliance with the DCS procedure, availability of another person to spend the night at the patient's home in the event of an emergency, living less than 1 hour from a hospital, and able to be contacted.

Preoperative exclusion criteria were the following:

Related to AA: complicated AA (CAA) on the basis of clinical features (sepsis), laboratory signs (renal failure), or radiologic signs (abscess, localized or generalized peritonitis, fecaliths, or pneumoperitoneum on CT scan or ultrasound).

Related to DCS: patient's refusal of DCS, contraindication to DCS (pain refractory to usual painkillers, another person not available to spend the night at the patient's home in the event of an emergency, living more than 1 hour from a hospital, and unable to be contacted).

Related to this specific study: diagnosis of UCAA between 12 PM and 7 AM, attending the emergency department over the weekend.

Intraoperative exclusion criteria were the following:

Related to AA: the presence a CAA (abscess, localized or generalized peritonitis, or fecaliths).

Related to the diagnosis: intraoperative finding of an alternative diagnosis.

Related to operation: associated surgical procedure (colectomy, cecectomy, or adnexectomy).

Preoperative management
All physicians in the emergency, radiology, anesthesiology, and surgery departments were aware of the DCS management of UCAA, as all were involved in the AppendAmbu trial.

The diagnosis of UCAA or CAA was established by the digestive surgeon in the emergency department. The diagnosis was based on clinical, laboratory, and radiologic data. The CT scan and ultrasound were performed and examined by a radiologist. The decision to propose DCS and include the patient in the study was taken and validated on admission by the digestive surgeon and the anesthesiologist. After being selected for DCS management of UCAA, patients received detailed information about the protocol, the DCS program, and the on-call surgeon's telephone number. All patients received a single dose of analgesic (tramadol hydrochloride/paracetamol) and antibiotic (amoxicillin and clavulanic acid 1,000 mg, or ofloxacin 200 mg + metronidazole 500 mg when the patient was allergic to penicillin). Patients took their treatment in the presence of the investigator. Three management plans were defined according to the time of patient's diagnosis (Fig. 1). If the patient was admitted between 12 PM and 7 AM, DCS was not proposed because the DCS department was not available. If the patient was admitted between 7 AM and 12 AM, DCS was proposed, the patient was admitted to the DCS department and underwent the procedure in the morning and was discharged in the afternoon. If the patient was admitted between 12 AM and 12 PM, the patient was discharged home and asked to return to the DCS department the next morning to undergo the procedure and was discharged in the afternoon.

Anesthesia protocol
No premedication was administered before anesthesia. In the operating room, patients were pretreated with an inspired oxygen fraction of 1 for 5 minutes. General
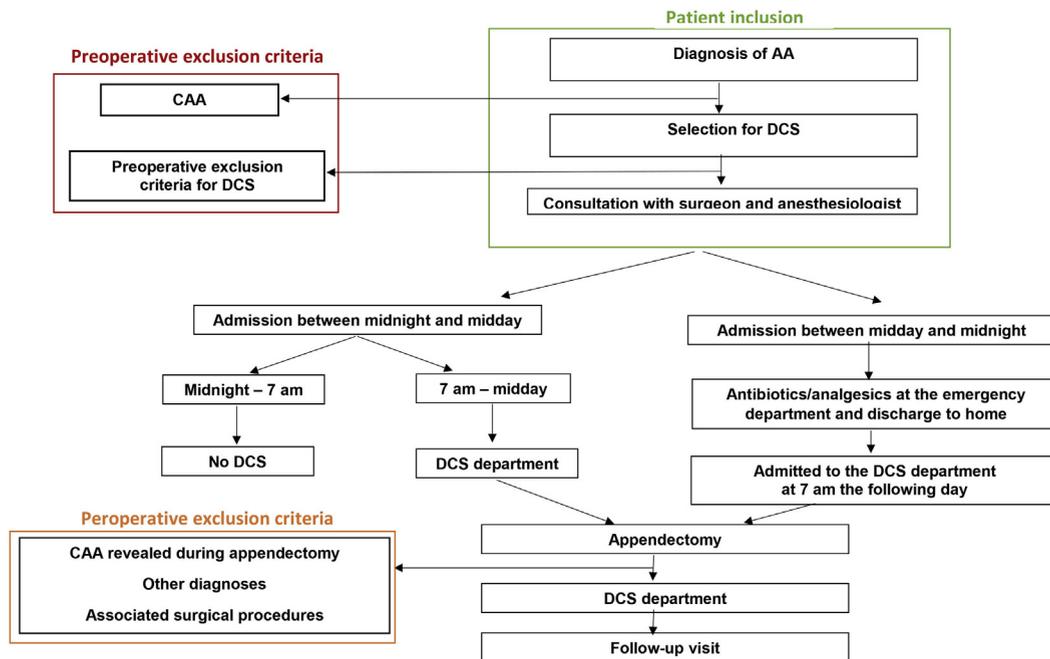
Figure 1. Study population and patient flow according to the time of diagnosis. AA, acute appendicitis; CAA, complicated acute appendicitis; DCS, day case surgery.

anesthesia was induced with propofol (2.5 mg/kg), sufentanil (0.5 μg/kg), and rocuronium (0.6 mg/kg) to facilitate tracheal intubation. An IV dose of 2 g cefazolin was administered at induction. Anesthesia was maintained with 4% to 6% desflurane and 0.1 to 0.25 μg kg^{-1} min^{-1} remifentanil. Mechanical ventilation was adjusted to maintain arterial oxygen saturation >95% and CO_2 between 30 and 35 mmHg with an inhaled oxygen concentration of 50%. Neuromuscular blockade was reversed in every case with neostigmine bromide 40 μg/kg and atropine 1 mg or sugammadex 2 to 4 mg/kg when the train-of-four ratio was >2. Postoperative analgesia was ensured by a combination of nefopam 20 mg, tramadol 100 mg, and acetaminophen 1 g. Patients received an IV injection of dexamethasone 8 mg and droperidol 0.625 mg on induction of anesthesia and ondansetron 4 mg postoperatively to prevent postoperative nausea and vomiting. Transverse abdominal plane block and incision infiltration were not systematically performed. When a nasogastric tube was placed during operation, it was always removed in the operating room at the end of the operation. Urinary tube and abdominal drain were never used. The patient was asked to urinate before the intervention.

Operative management

Regardless of the type of appendicitis (UCAA or CAA), patients were asked to urinate before anesthesia to avoid the need for a bladder catheter. Appendectomies were performed laparoscopically using the 3-port technique (1 at the umbilicus, 1 in the left inferior quadrant, and 1 in the suprapubic position). All of abdominal cavity was explored to determine whether or not AA was complicated. Whenever possible, a pus sample was taken intraoperatively for bacteriologic examination and additional antibiotic therapy in the presence of postoperative infectious complications. Appendectomy was performed with coagulation of the meso-appendix and section of the appendix at its root using an endoloop. The surgical specimen was removed in a bag and abdominal drains and nasogastric tubes were not used.[12]

For patients with UCAA, in accordance with the French Society of Anesthesia and Resuscitation Medicine's guidelines,[13] patients were given a single IV injection of amoxicillin plus clavulanic acid (2 g) or ofloxacin 200 mg + metronidazole 500 mg (when the patient was allergic to penicillin) on induction of general anesthesia and did not receive any antibiotics thereafter.

Postoperative management

After operation, all patients who had been admitted between 7 AM and 12 AM or between 12 AM and 12 PM were systematically transferred to the DCS department. Patients admitted between 12 PM and 7 AM were hospitalized in the conventional ward. Admission to the DCS department was organized preoperatively in the emergency department. Two DCS beds are devoted to

emergencies (mainly for digestive and orthopaedic operations). When the patient was admitted on the day of operation, the surgeon called the DCS department to book a bed for the patient and, when the patient was admitted in the evening or in the night, the surgeon sent an email to book a bed for the next morning.

During the postoperative period, on arrival at the DCS department, a clear liquid diet was commenced immediately after operation, and a soft diet was introduced 2 hours later. Patients were discharged home with oral analgesia when they tolerated a liquid diet. When the patient was unable to be discharged, he or she was admitted to the Department of Digestive Surgery. When the patient was able to be discharged, he or she was given a detailed information sheet providing instructions, including contact numbers for urgent advice in an emergency. The telephone numbers connected to the DCS specialist nurse during normal working hours (8 AM to 6 PM) and to the on-call surgical team outside of these times. Patients were advised to contact the team by telephone or in person if they experienced any of the following symptoms: nausea, vomiting, abdominal distension, or fever. Each patient was contacted by telephone by a nurse 24 hours after discharge from the DCS department. The follow-up assessment was performed in the outpatient clinic on postoperative days 7 and 30.

Primary end point
The primary end point was the DCS success rate (length of stay <12 hours) in the ITT population (all patients with UCAA) and in the per-protocol (PP) population (population with UCAA and no preoperative or intraoperative exclusion criteria). The DCS success rate in this study (AppendAmbu II) was compared with the DCS success rate in the AppendAmbu study.

Secondary end points
The secondary end points were the following:

1. Determine the DCS quality criteria (ie the rate of unplanned consultations, unplanned hospitalizations, unplanned reoperations) and to compare these rates with those of the AppendAmbu study.
2. Evaluate and compare the morbidity and mortality of DCS for UCAA with the morbidity and mortality of conventional hospitalization for UCAA using Clavien classification[14] and the Comprehensive Complication Index.[15] For evaluation of this end point, patients of the current study (AppendAmbu II) and patients of the AppendAmbu study managed by DCS were pooled and compared with patients managed by

conventional operation during the same period (mainly due to organizational contraindications to DCS).

Externally validate the St Antoine score[10] for the selection of patients for DCS based on evaluation of the pooled AppendAmbu and AppendAmbu II populations. Patients with preoperative UCAA (n = 100 in AppendAmbu and n = 95 in AppendAmbu II), patients with intraoperative CAA (n = 12 in AppendAmbu and n = 30 in AppendAmbu II), patients with an associated procedure (n = 2 in AppendAmbu and n = 7 in AppendAmbu II), and the PP population (n = 83 in AppendAmbu and n = 57 in AppendAmbu II) were included in this analysis. The overall population comprised 386 patients. The St Antoine score was not available for 59 of these patients and was therefore analyzed for 327 patients.

Diagnosis of uncomplicated acute appendicitis
The diagnosis of UCAA was established in the absence of any signs of CAA. Preoperatively, UCAA was defined on the basis of clinical examination (pain not refractory to usual painkillers, no sepsis) and laboratory parameters (no signs of renal failure). The definitive diagnosis of UCAA was based on CT scan or ultrasound and required clear visualization of the appendix (appendix diameter >6 mm), and absence of any of the following criteria of CAA (abscess, localized or generalized peritonitis, fecaliths, or pneumoperitoneum).[2] The intraoperative diagnosis of UCAA was defined by the absence of abscess, localized or generalized peritonitis, or fecaliths. Clear liquid in the right iliac fossa or pelvis was not considered to be a sign of CAA.

Day case surgery quality criteria
The quality criteria used in this study were the International Association for Ambulatory Surgery (www.iaas-med.com) quality indicators for DCS outcomes (ie unplanned overnight admission, unplanned consultation, unplanned hospitalization, and unplanned reoperation) in patients in whom DCS management was successful. The unplanned overnight admission rate corresponds to the proportion of patients who were not discharged in the evening after the surgical procedure and who were hospitalized for at least 1 night. The unplanned consultation rate represents the proportion of patient attending a consultation for a postoperative complication during the first month of follow-up. The unplanned hospitalization rate corresponds to the proportion of patients who were readmitted after appendectomy. Finally, the unplanned reoperation rate is defined as the proportion of patients

who were underwent operations after their post-DCS discharge.

Predictive factors of success of ambulatory surgery (St Antoine's score)

This score was constructed in the overall population of patients with AA to determine the day 1 successful discharge rate according to the following 5 criteria related to AA exclusively (and not to research or organizational criteria or DCS): BMI <28 kg/m², preoperative C-reactive protein (CRP) level <30 mg/dL, preoperative leukocyte count <15,000/mm³; diameter of the appendix <10 mm, and no radiologic signs of perforation (ie no abscess and no local peritonitis on CT scan). The absence of any of these criteria corresponds to a 0% day-1 discharge rate, and the presence of all 5 criteria corresponds to a 92% day-1 discharge rate.

Ethical approval

This retrospective study (AppendAmbu II) was reported to the Commission National de l'Information et des Libertés (Study DRCI T181). The AppendAmbu study was approved by the Agence Nationale de Sécurité du Médicament et des Produits de Santé, the Comité de Protection des Personnes-Nord Ouest II Ethics Committee, and the Commission National de l'Information et des Libertés. The study was registered at www.ClinicalTrials.gov (ID NCT01839435).

Statistical analysis

The characteristics of the study population are described in terms of mean ± SD and median (range) for quantitative variables and frequency and 95% CI for qualitative variables. For analysis of the primary end point, the DCS success rate is reported with a 95% CI. For analysis of the secondary end points, the unplanned consultation, unplanned readmission, and unplanned reoperation rates are reported as percentages. The morbidity (assessed by Clavien-Dindo classification) is expressed as a percentage for each rank. Statistical analysis was performed with SAS software, version 9.2 (SAS Institute). A p value ≤ 0.05 was considered to be statistically significant.

RESULTS

Population

From January 2016 to September 2017, two hundred and ninety-six patients underwent operation for AA, comprising 176 men (59%) with a mean age of 38 ± 18 years. All procedures were performed by laparoscopy without conversion. Among these 296 patients, 201 (68%) had UCAA (ITT population) (Table 1). Among the patients with UCAA, 107 (53%) patients presented preoperative exclusion criteria and 94 (47%) met the preoperative inclusion criteria of this study.

Thirty-seven (18%) of these 94 patients presented intraoperative exclusion criteria (Fig. 2). The remaining 57 (28%) patients presented no preoperative or intraoperative exclusion criteria (PP population). The PP population represents 19.2% (57 of 296 patients) of the entire population of patients undergoing operations for AA. Thirty-one (54%) of these 57 patients were admitted between 12 AM and 12 PM and were discharged home before the operation.

Primary end point

The proportion of patients with successful DCS management (AppendAmbu II study) was 27% (54 of 201) in the ITT population and 95% (54 of 57) in the PP population. In the AppendAmbu study, the success rate was 32% in the ITT population and 92% in the PP population. The success rate was not significantly different between AppendAmbu II and AppendAmbu in the ITT population (p = 0.2) or the PP population (p = 0.2). The success rate of patients discharged home before the operation (n = 31) was 100%.

Secondary end points

Day case surgery quality criteria

Eight of the 54 (15%) patients with successful DCS management attended an unplanned consultation for

Table 1. Characteristics of the AppendAmbu and AppendAmbu II Populations

Characteristic	AppendAmbu study (n = 340)	AppendAmbu II study (n = 296)	p Value
Male sex, n (%)	181 (53)	176 (59)	0.1
Age, y, mean ± SD	35 ± 18	38 ± 18	0.04
BMI, kg/m², mean ± SD	24 ± 6	25 ± 8	0.6
Time of consultation, n (%)			0.2
Midnight to 7 AM	72 (21)	74 (25)	
7 AM to mid-day	32 (9)	34 (12)	
Mid-day to midnight	236 (70)	187 (63)	
Complicated acute appendicitis, n (%)	100 (29)	95 (32)	0.4
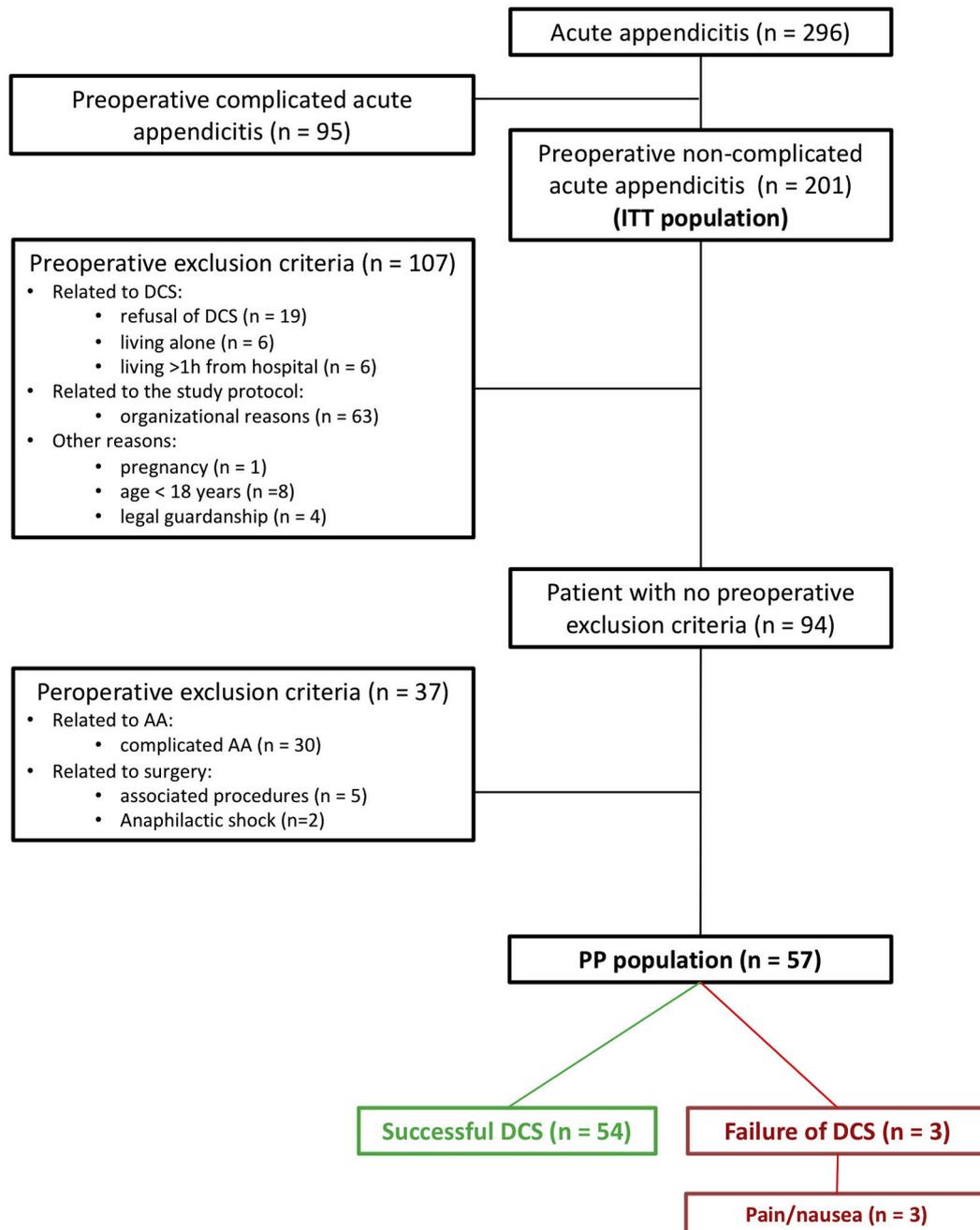
Figure 2. Study flowchart. AA, acute appendicitis; DCS, day case surgery; PP, per protocol; ITT, intention-to-treat.

vomiting (n = 1), right lower quadrant pain (with no laboratory or CT abnormalities) (n = 5), and deep abscess treated by antibiotics (n = 1) and treated by radiologic drainage (n = 1). Two patients (4%) with abscess who attended an unplanned consultation subsequently had an unplanned hospitalization. No patients required an unplanned reoperation. The unplanned consultation (p = 0.8), unplanned hospitalization (p = 0.9), and

unplanned reoperation (p = 0.9) rates were not significantly different between the AppendAmbu and AppendAmbu II studies.

Morbidity
Postoperative morbidity according to the Dindo-Clavien classification of patients managed by DCS (AppendAmbu and AppendAmbu II populations) (n = 140) was not

significantly different from that of patients managed by conventional hospitalization (n = 256) during the same study period (p = 0.7). According to the Comprehensive Complication Index classification, postoperative morbidity was lower after DCS than after conventional operation (5.77 vs 9.48; p = 0.0009) (Table 2).

Validation of factors predictive of success of day case surgery (St Antoine score)

The DCS rate for the 327 patients, according to the St Antoine score, was 0% (0 of 7) for patients with a St Antoine score of 0, 6% (2 of 31) for patients with a St Antoine score of 1, 9% (7 out of 78) for patients with a St Antoine score of 2, 37% (29 of 79) for patients with a St Antoine score of 3, 68% (52 of 77) for patients with a St Antoine score of 4, and 80% for patients with a St Antoine score of 5 (28 of 35) (p < 0.0001).

DISCUSSION

The AppendAmbu study confirmed the feasibility of DCS for UCAA with a 31.5% success rate in the ITT population and a 90.5% success rate in the PP population, but these results could be related to the context of the protocol. This study (AppendAmbu II) confirms the real-life feasibility of DCS for UCAA with a 27% success rate in the ITT population and a 95% success rate in the PP population, and confirms the high success rate in selected patients. Appendectomy for UCAA is a good indication for DCS, but remains challenging, as emergency digestive surgery procedures are usually not managed by DCS. Discharging a patient before operation can be a source of anxiety for the surgeon and for the patient. The AppendAmbu study was designed to build a rigorous protocol for the DCS management of emergencies by reducing the anxiety in relation to DCS.

These outcomes are probably due to the use of a dedicated DCS circuit in the DCS department, with 12 hours opening and patients must be discharged at the end of the opening of the DCS department, as any of the other patients managed in DCS. It is an important point, as the development of DCS must be supported by optimizing validated elective indications and by proposing new elective indications, such as fundoplication and sleeve gastrectomy,[16,17] as well as emergency procedures.[3,5,9,10,18-20] The DCS teams are trained in the management of DCS, which should improve the success rate. The DCS rate remained stable but did not increase compared with the AppendAmbu study.

The main issue remains how to increase the DCS rate, as the safety of DCS for UCAA makes it a challenging strategy for antibiotic therapy because antibiotic therapy requires hospitalization for 5 days and is associated with up to 29% of failures.[2]

One of the limitations of this study is that, for safety reasons, the inclusion criteria were limited and only 57 of the 296 (19.2%) patients undergoing operations for appendicitis during the study period were eligible for DCS. The PP population represents only 19.2% of the entire population. In real life, to increase the number of patients managed by DCS, this procedure must be clearly explained to the patients before the operation to avoid refusal (n = 19 in this study). Despite the team's extensive experience, the DCS refusal rate remains high, which also highlights the need to include the patient in the decision-making process, which cannot be performed without the patient's consent and understanding based on adequate information about the safety of DCS. Complicated AA, which represents about one-third of all patients undergoing operations for appendicitis (32.4% in a nationwide cohort in the UK), might also be suitable for DCS. It could be particularly useful in patients with localized peritonitis (pus in no more than 2 quadrants), as recently reported by our team in a dedicated video survey study (Mariage and colleagues, unpublished data, 2019), for whom a strategy without

Table 2. Comparison of the Morbidity and Mortality of Uncomplicated Acute Appendicitis Managed by Day Case Surgery and Conventional Hospitalization

Variable	Day case surgery* (n = 140)	Conventional hospitalization (n = 256)	p Value
Clavien classification, n (%)			0.7
0	116 (82)	215 (84)	
1	14 (11)	21 (8)	
2	2 (1)	8 (3)	
3a	3 (2)	4 (1,5)	
3b	5 (4)	5 (2)	
4a	0 (0)	2 (1)	
4b	0 (0)	0 (0)	
5	0 (0)	1 (0.5)	
Comprehensive Complication Index, mean (SD)	5.77 (0−53.8)	9.48 (0−55.5)	0.0009

*AppendAmbu and AppendAmbu II study populations.

postoperative antibiotic therapy is currently being studied in the ABAP (The Value of Post-operative Antibiotic Therapy After Laparoscopic Appendectomy for Complicated Acute Appendicitis [Other Than for Generalized Peritonitis]) trial; ClinicalTrials.gov ID NCT03688295). However, the definition of uncomplicated appendicitis remains unclear. In our study, it was defined as the absence of abscess, localized or generalized peritonitis, fecaliths, or pneumoperitoneum. It should be noted that the definition of localized peritonitis is controversial in terms of the macroscopic aspect of the liquid (from serosity to pus) and the number of quadrants contaminated by pus. It is therefore easier to first define uncomplicated appendicitis (ie catarrhal appendicitis without any liquid in the abdomen) and then define complicated appendicitis as any appendicitis that is not uncomplicated. It should also be noted that in a recent report on a randomized controlled trial in children, St Peter and colleagues[21] defined complicated appendicitis as appendicitis with a hole in the appendix or with fecaliths; this excluded abscesses and local peritonitis from the definition because the latter conditions were associated with a lower rate of postoperative complications than the former conditions (14% vs 18%, respectively). Nevertheless, St Peter and colleagues' study is the only one to have specified the nature of complicated appendicitis; all other studies have referred to "complicated appendicitis" without giving any details. However, the risk of postoperative complications is not itself a contraindication to DCS, as complications can happened after patient discharge even in traditional hospitalization, and most patients with CAA have a preserved general condition and might be good candidates for DCS.

Patients suitable for DCS appendectomy must be carefully selected during the preoperative period using a DCS success predictive score. To increase the number of patients undergoing DCS, it would also be necessary to reassure the patient by suggesting postoperative follow-up at home with "smart devices" or home nurse follow-up. It is also important to propose DCS to patients admitted over the weekend or between midnight and 7 AM by allowing around-the-clock discharge.[20]

In the current study, we also externally validated the St Antoine score,[10] which is very useful to ensure objective patient selection. This score included a BMI <28 kg/m², preoperative CRP level <30 mg/dL, preoperative leukocyte count <15,000/mm³; diameter of the appendix <10 mm, no radiologic signs of perforation. In this study, the success rate ranged from 0% for a score of 0 to 80% for a score of 5. Day case surgery is therefore proposed to patients with a St Antoine score of 4 or 5. Among these data, CRP level is not usually ordered in the workup of appendicitis; however, some data suggest than CRP is valid in distinguishing complicated and uncomplicated appendicitis. In 1999, Grönroos and colleagues[22] evaluated CRP in a cohort of 300 patients and found that CRP value was superior to leukocyte count in reflecting complicated appendicitis. In their study, the mean value of CRP was 99 mg/L in complicated appendicitis and 31 mg/L in uncomplicated appendicitis.[22] In addition, in a publication by our group, we found that age younger than 23 years and CRP <18 mg/L were associated with a predictive positive value of 100% for a length of stay <24 hours.[3]

CONCLUSIONS

It is legitimate to question the purpose of DCS appendectomy. Day case surgery constitutes a progress in surgery as a result of enhanced recovery programs. Day case surgery avoids unnecessary prolonged hospitalization and allows the patient to stay at home safely, as there is no excess risk of complications.

Author Contributions

Study conception and design: Sabbagh, Masseline, Grelpois, Ntouba, Dembinski, Regimbeau
Acquisition of data: Masseline, Grelpois
Analysis and interpretation of data: Sabbagh, Masseline, Grelpois, Ntouba, Dembinski, Regimbeau
Drafting of manuscript: Sabbagh, Regimbeau
Critical revision: Sabbagh, Masseline, Grelpois, Ntouba, Dembinski, Regimbeau

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