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Surgical safety checklist in pediatric surgery

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ABSTRACT

Patient safety still remains as one of the biggest challenges for healthcare professionals. Surgical adverse events comprise 8% of all iatrogenic complications, half of them being easily preventable with simple checkup methods. Especially in pediatric surgery, where not only meaningful differences in anatomy or treatment response lie, but more importantly limited communication with the patient occurs, additional precautions have to be undertaken. In 2008, as a result of Safe Surgery Saves Lives campaign, Surgical Safety Checklist was introduced. A standardized checklist of all crucial perioperative steps is meant to be performed in every operating theater, ideally under all circumstances. The aim of our study was to present the current views and effectiveness of implementation of surgical safety checklists in pediatric surgery settings. We analyzed substantial articles on implementation and challenges of surgical checklist in pediatric surgery from period 2008-2018. Within 310 articles of PubMed database, 10 substantial articles on pediatric surgery safety were identified and reviewed. 70% of articles discussed the implementation of the checklist and post-implementation improvements, 20% included healthcare and parents attitude towards safety checklists. One article presented the variation of the surgical safety checklist in pediatric surgical and ambulatory settings. Most of the articles noted the prevention of adverse events correlated with the usage of the checklist, as well as positive attitude of healthcare providers and patients family towards checklist implementation was noted. Main challenge was the fidelity of the completion, especially in emergency settings. The Surgical Safety Checklist unifies the process of avoiding human error in surgery at all costs. Reviewed research presents improvements in prevention of adverse events in pediatric surgery, as well as innovative solutions for issues related mainly to pediatric patients, such as inclusion of guardians or even patients in safety check process, or implementing procedural or bedside safety checklists.

Keywords: Pediatric surgery, surgical safety, patient safety, surgical safety checklist

1. INTRODUCTION

1. 1. Pediatric surgery and adverse events

Pediatric surgery evolved from general surgery as its sub-specialty, dealing mostly with congenital malformations, abdominal wall defects, chest wall abnormalities and childhood tumors. Starting from 20th century, the achievements of William E. Ladd, father of pediatric surgery (with his co-authored first textbook *Abdominal Surgery and Infancy of Childhood*) and C. Everett Koop, pioneer in endotracheal anesthesia of infants, gave hope to the youngest patients for the chance of living and fighting the congenital conditions previously leading to disabilities. [1-3]

Pediatrics is a specialty which requires the double care for the patients, not only because of the meaningful differences in anatomy, treatment response, possibility of diagnostic procedures than in internal medicine, but also because of the limited communication with the patient, often unable to voice their complaints or precisely describe and locate the symptoms. The Canadian study of adverse events in children identified 9,2% rate of iatrogenic complications in 3700 children, in which 45% could be preventable. [4] Pediatric surgery also differs significantly from adult surgery, mostly in terms of healthcare infrastructure, with lower risk of perioperative death (except congenital cardiac and newborn surgery), however with still high risk of perioperative adverse events. [4;5] The rates of adverse events are still lower than in adults, but we can't exclude the possibility of post-operative life-threatening events in pediatric surgery. [6;7] Despite the fact that international statistics lack of information of rate of adverse events in pediatric surgery, previously quoted Canadian study claims that among pediatrics adverse events, pediatric surgery was the discipline where it occurred the most frequently. [8]

1. 2. How to prevent adverse events in medicine - current solutions

Despite successful wars with epidemics, wounds, safe child delivery and painless surgeries with newest anesthesiology and surgical equipment, modern medicine still faces both old and new iatrogenic mistakes, which should be avoided by all costs. In modern medicine several several Patient Safety Goals are identified, such as most popular antimicrobial resistance, polypharmacy interactions, health care associated infections. Studies reveal that steps which require communication are still sensitive to human errors. Communication in healthcare, patients identification, proper anaesthesiological monitoring and safe usage of surgical equipment are vital steps in provision of safe surgery. [9] Starting from 2002, World Health Organization and World Alliance for Patient Safety initiated the Safe Surgery Saves Lives campaign, which in 2008 resulted in introduction Surgical Safety Checklist to modern surgery. [10]

1. 3. Surgical Safety Checklist

Surgical safety checklist is a set of items which have to be checked before any surgery and can be performed in any of the operating theatres. This safety check consists of 3 parts: sign in, time out and sign out, which should be applied respectively before induction of anaesthesia, before skin incision and before patient leaves the operating room. [11]

During the sign in procedure, the team confirms patients identity for the first time and marks the site of the surgery. Anaesthesiological team performs the anaesthesia safety check and check up of pulse oximeter. The team confirms significant allergies, possible airway difficulties, aspiration risk and estimated blood loss risk assessment. Second part of the checklist, the time out, begins with the operating team confirming roles and names of each member, and all 3 sub-teams - Surgical Team, Anaesthesiologist Team and Nurses Team confirm Patient-Side-Procedure details. Concerns about possibilities of critical events are being described by each team. The check up also includes the antibiotic prophylaxis within last 60 minutes and the availability of the necessary imaging equipment. During third, last past- sign out nurse confirms the procedure, amount of instruments used, labeling of taken specimen, lastly, before patient leaves the OR, key concerns from all the subteams are being discussed. [11]

Table 1. Phases of the Surgical Safety Checklist. Prepared by authors.

Phase	Time of the procedure	Items checked	Person responsible
Sign in	Before induction of anaesthesia	Identity of patient and site of surgery Anaesthesia safety check Pulse oximeter Allergies/airway difficulties/blood loss risk	Leader + anaesthesia team
Time out	Before skin incision	Patient/Site/Procedure Team introduction and confirming roles Critical events possibility Antibiotics and imaging	Leader + All Teams (Surgical, Anaesthesia, Nursing Teams)
Sign out	Before patient leaves the theater	Procedure performed, Counting instruments, Labeling the specimen, Key concerns	Leader + Nursing Team

2. AIM OF THE STUDY

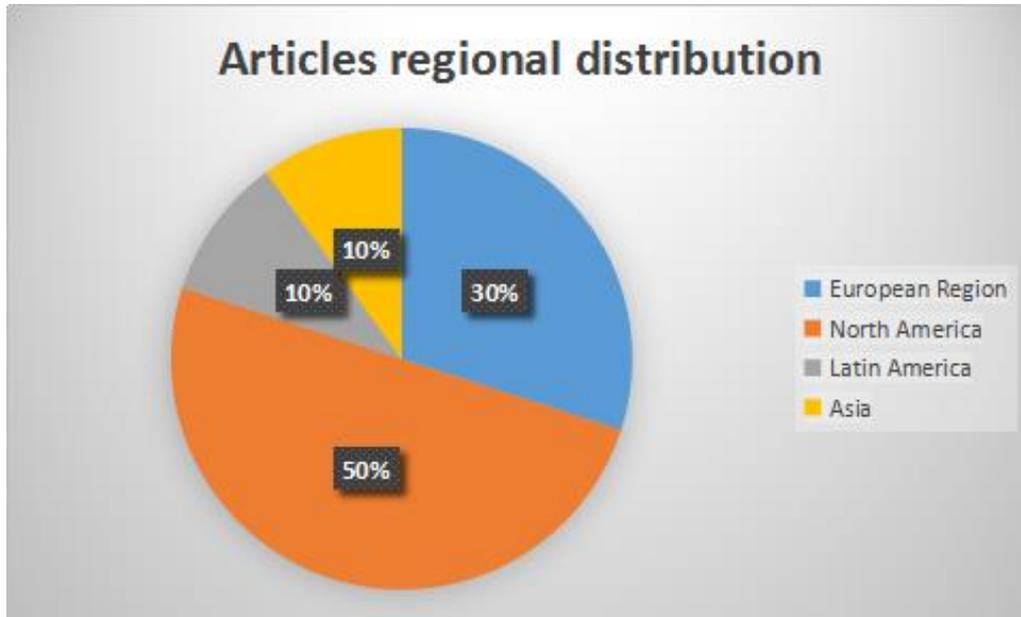
The aim of the study is to present the current views and effectiveness of implementation of surgical safety checklists in pediatric surgery settings.

3. METHODS

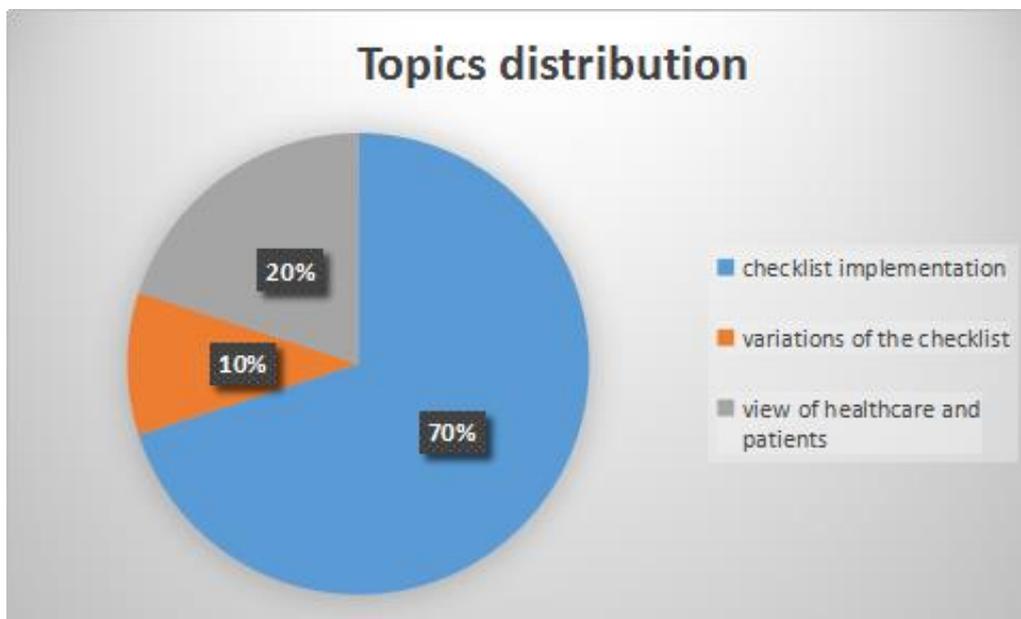
Substantial articles on surgical checklist in pediatric surgery from period 2008-2018 in the Asian, European and American regions have been analyzed.

Among 310 articles in PubMed Medline database, 10 articles were selected for analysis.

4. RESULTS



Graph 1. Regional distribution of research. Prepared by authors.



Graph 2. Topics distribution. Prepared by authors.

Among 10 articles, there was a certain variety of topics discussed regarding patient safety in pediatric surgery settings. We decided to focus on:

- successful checklist implementation and improvements made (7 articles)
- variations of the checklist in pediatrics, including Pediatric Surgery Safety Checklist (1 article)
- views of health care and parents on surgical safety checklist (2 articles)

Additionally, challenges in checklist implementation, mistakes and suggestions for improvement were noted in 4 of the reviewed articles.

4. 1. Checklist implementation

Table 2. Checklist implementation in pediatric surgery settings. Prepared by authors.

Study	Country	Number of cases	Checklist applied in:	Completeness	Perioperative errors	Challenges
Oak et al. (2015)	India	3000 cases	98,2%	95,7%	0,3% near missed catastrophe 2,6% no signed consent	Emergency surgeries, Application by junior staff, incomplet-ed sign out phase
Bellora et al. (2013)	Italy	61 cases	100%	-	Occurred in 11,11% of errors	-
McGinlay et al. (2015)	Romania	40 cases	100%	55%	Not included in analysis	Team introduction in Time Out never performed, only 40% of professionals received training
Bartz-Kurycki et al. (2017)	USA	603 cases	100%	48-55%, Debriefing in more than 90% of cases	-	-
Levy et al. (2012)	USA	142 cases	100%	99% of Patient/Side/Procedure 97% timeout beginning	-	Only 31% of items checked before incision

Skarskard E. (2016)	Canada	15 hospitals specialized in pediatric surgery	-	-	in 40% of the hospitals the errors identified, including“ nearly missed catastrophe” -in 87% of hospitals, the safety culture in OR improved	-
O’Leary et al. (2016)	Canada	28772 admissions (14458 before and 14314 after the checklist introduction	-	-	4,08% before introduction and 4,12% after introduction of the checklist -no statistical difference	No reduction of perioperative complications as well as reduction in healthcare resources

In study by Oak et al., in India after checklist implementation, in over 3000 cases in years 2011-2013, the checklist was used completely in 95,7%, in 1,8% not used at all and in 2,5% was incompletely filled in sign out phase. In sign out, instrument counts were always performed and no errors was found in this part of the third phase. In this period, no major perioperative errors occurred, 0,3% of cases classified as “near missed catastrophe”, in 0,1% patients undergoing major resective surgeries there was a wrong side noted in the case notes consent forms. In 2,6% cases the consent form was not signed by the guardians of the patient. In 0,17% preoperative antibiotic orders were missing, in 0,13% the identification tag fell from the patient during transport to the OR, and in 3,6% cases junior staff missed mentioning the side of procedures. It was noted that in 1,8% cases, children had the same names and surgical procedure on the same day to be performed (eg. circumcision). [12]

The study revealed successful checklist implementation in pediatric surgery settings and stated several aspects of possible improvements. Within two study limitations noted were firstly, less information on how significant percentage of those surgeries were emergency surgeries and how many of the surgeries have been performed by the junior staff (as explained by authors, junior doctors had a higher tendency in omitting the full checklist implementation, especially in emergency situations).

In Italian study, among 61 completed checklists, 189 errors were counted, most of them (59,78%) again, during sign-out phase. The implementation of the checklist led to reduction of the adverse events in 88,89% cases -within the percentage cumulative frequency of nearmiss. The adverse events occurred in 11,11% of cases. [13]

In Brasov study in 2015, among 40 surgeries observed after checklist implementation, it was found to be filled in 55% of all items, and the performance did not correlate to numbers of staff, surgeries per day, specialty or emergency/elective situation. Study revealed that the Team introductions during Time Out were never performed, and in Sign Out only 2 times the

key considerations for recovery were discussed. Here also, as noted by the author, the outcomes and effects of the implementation on patients condition was not included in the analysis. [14]

USA study (Bartz-Kurycki et al.) revealed in 2 years span (2014-2016) out of 603 cases observed the debriefing was conducted in above 90% of cases, growing from 90.6% in 2014 to 94.9% in 2016, with the relatively unchanged median of items checked. Full completion was achieved only in about 50% of cases with no debriefing in 9% in 2014 and 2015, 5% in 2016 ($P < 0.001$). [15]

Next US study by Levy et al. tried to identify the stages where the preincision components of the checklist were not performed. During 7 weeks of study, among 142 surgical cases, the hospital data showed 100% compliance with sign in and timeout procedures, however study demonstrated that none of the cases executed all items. The average amount of items checked before incision was 31%, with most commonly confirmed patient name, procedure (99%) and timeout in the beginning of the checklist 97%. The correctness of the check up remained the same during the study period. [16]

Canadian study by Skarskard E. compared the ways of implementation of the surgical checklist among 15 children hospitals in Canada. Firstly, within the participation of the 3 sub-teams (anesthesia, surgery, nurse) - 33% of teams required representatives of all sub-teams to be present during the implementation of all phases, in 47% its said that roles of anaesthesiologist and surgeon can be represented by junior doctors, since they are more familiar with patient and planned treatment. As for the execution, certain variability is described - 20% read the checklist out loud, 27% prefer a free flowing conversation including all the tasks, and 33% use a scripted checklist. In any of the hospitals there is no requirements set on who should be the leader of the checklist implementation. Within 12 months, in 40% of the hospitals the errors were identified with usage of the checklist, and the “never events”, such as wrong patient, side or procedure, were prevented due to the check up. In 87% of hospitals, the safety culture improved in the operating room. The surgeons in chief claimed in 26% of wards the OR efficiency improved, 54% saw no particular effect on efficiency, and in 20% in their opinion, it had diminished. [8]

Next Canadian study (O’Leary et al. 2016) included the time period of 2 years, 1 year before and 1 year after the checklist implementation (between 10.2008 and 09.2011), total 28772 admissions (14458 before and 14314 after the checklist introduction). The study aimed to specify the significant differences in 1) mortality and complication rates, 2) healthcare utilization after the implementation of the checklist. Among 116 admissions diagnosis identified in the study, three most common were: acute appendicitis (14.6%), oral cavity or pharynx surgery (12.6%), orthopedic surgery of upper body or limb (8.8%) Perioperative complications occurred within 30 days after surgery, such as renal failure, cardiac arrest, deep vein thrombosis etc., were found in 4,08% of cases in the prechecklist and 4,12% in post-checklist groups, which after adjustments is considered as a no significant change by the authors (95% CI 0.90–1.14, $p = 0.9$). The health care resources usage, such as length of the stay, unplanned return to OR, emergency visit after 30 days after the surgery were the secondary goal of the study. The length of stay was different between pre- and postchecklist (10 days versus 9 days) and even after adjusting the confounding factors was still significant ($p < 0.001$). Unplanned return to the OR were observed in 0,27% and 0,24% pre- and post-checklist implementation cases, with no significance ($p = 0,6$). Emergency visits after 30 days were 3.35% and 3.53% pre- and postchecklist with no significance ($p = 0.4$). The conclusion

of this study was that despite the evidence of checklists improving patient safety in surgical settings, in Ontario case the implementation was not associated with reduction of perioperative complications and reduction of health care resources utilization after surgery. [17]

4. 2. Variations of the checklist in pediatric settings

4. 2. 1. 7:35 Morning Huddle

In Canada, apart from the regular surgical checklist procedures, 40% of the hospitals use a 7:35 huddle, or morning huddle, which is a meeting of all surgical sub-teams 10 minutes before the first operated case. The meeting consists of confirmation of all scheduled cases, equipment, blood and antibiotic prophylaxis requirements, as well as surgical or anaesthesiological concerns. The meeting, usually led by surgeon or anaesthesiologist in charge, helps the whole team to fully understand the procedures and assure the quality of patient safety during performed surgeries. [8]

4. 2. 2. Pediatric Surgical Safety Checklist

Another variation of the surgical checklist in pediatric surgery settings is the Pediatric Surgical Safety Checklist. The Children Hospital Boston, Massachusetts developed a modifications of the original checklist both for the OR and other invasive procedures. [18] The changes have been made in order to provide coordinated teamwork, clear communication and improve the knowledge and experience - the three aspects which, if insufficient, could become the leading causes of the surgical errors. [19]

Within the operating checklist, the roles of each team members was added in order to provide the leaders for each stage and each item of the checklist. In this example, during sign in phase led by Circulator, apart from regular items, compression boots for DVT prophylaxis and warmers to prevent hypothermia are checked. Also, for the patients and site identification, patient and parents are engaged (if it is applicable). In the time out led by Surgeon, the verification by main Surgeon/Anaesthesiologist/Nurse are being made, as well as the last item "STOP! Any questions from the Team?" is being added. Lastly, in the sign out led by Surgeon, Surgeon verifies the procedure, Circulator or Scrub the final counts, labeling and equipment problems, and key concerns discussion with all team members is included.

The second type of pediatric checklist - Pediatric Procedural Safety Checklist - was implemented in pediatric cardiac catheterization laboratories, endoscopy suites and interventional radiology departments. This checklist resembles the original WHO version, except the differences in leaders of each step (sign in by the Registering Nurse, time out and sign out by the Clinician) and during time out, verification by the Nurse of the blood or cross-match, as well as medications/solutions labeled in the field.

Lastly, the third type of pediatric safety check- Pediatric Bedside Safety Checklist- is applicable to emergency departments, dental clinics, intensive care units, ambulatory clinic or treatment rooms, and here the difference with WHO version is the Clinician leading the process of all phases of the procedure.

The researchers proved within 7-months time frame (July 2009 - February 2010) compliance in most of the cases above 90% in all of the 3 checklists in the particular phases, with the highest result of the Pediatric Procedural Checklist, then Surgical, lastly Bedside Safety Checklist. During the audit before the actual implementation, it was found that several

“near misses” have been found by the team members (no antibiotics prophylaxis, no consent, missed equipment etc), which proved the necessity of implementation of the safety checklists in the pediatric surgery settings, however no post actual implementation results have been shared within reviewed article. [18] According to our research, this type of checklist was not announced to be practiced in other hospitals.

4. 3. Patients and parents views

Table 3. Guardians and healthcare views on surgical checklist depending on method used.
Prepared by authors.

Study	Country	Method Used	Number of cases	Guardians views	Healthcare views
De Oliveira Pires MP et al. (2015)	Brazil	The Path of My Surgery Questionnaire	60 cases	reduction of child anxiety in 83,3%	No information
Corbaly MT et al. (2014)	Dublin	Guardian involvement in sign in procedures	42 cases	100% think the step should be obligatory, 97,6% of site and procedure was correct	100% surgeons, 88% nurses, 76% anaesthesiologists Consider the step a justifiable addition

Two studies under review focused on the patients’ and parents’ perceptions of the surgical safety and checklists implementation. Another Pediatric Surgical Safety Checklist variation was held as a questionnaire for 60 children of average age 7,5 years old and their guardians in Brazil in 2012. [20] The aim of this study was to engage the patient and family in preoperative safety measures as well as to reduce anxiety due to upcoming surgery in pediatric patients. “The Path of My Surgery”, handed in to the patients and their families was a 12-items checklist, where patient had to mark the performed tasks by “X” or with a drawing. The items included the name of the patient, date of procedure, “*I won a bracelet with my name, the nurse explained what will happen to me here at the hospital, the nurse asked me if I had allergies, the nurse told me that I cannot eat or drink anything*” etc. There was no statistical difference between the age, education, kinship of family member and filling in of the checklist. The question regarding removing accessories, earrings, rings, piercing was filled in mostly by older children and this result was statistically significant. Also, the guardians considered this tool as a reduction of child anxiety in 83,3% and rated the materials in most of cases as great (63,3%) or good (36,7%). [20]

The study from Dublin also included the parental involvement in performed sign in procedures (confirmation of patient, surgery, site and given written consent). Among 42 patients admitted and accepted to the study all parents agreed that this step should be obligatory for pediatric surgery procedures and considered their participation as a step in improving patient safety. 97,6% claimed site and procedure were correct. Among the staff, 100% surgeons, 88% nurses, 76% anaesthesiologists felt it was a justifiable addition, and all of the staff considered this step as an improvement in pediatric surgical safety. [21]

5. DISCUSSION

It is confirmed that the occurrence of adverse events in medicine is still high, up to 8%. Among them, the surgical mistakes occur in up to 25% of patients, in developing countries - to 50% (WHO Surgical Safety Factsheet. Retrieved 31/12/2017) Half of surgical iatrogenic events could be preventable. We need to remember, that healthcare is not equal in all regions and that the Universal Health Coverage is still a goal rather than reality, which expresses in eg. mortality from general anaesthesia in Africa, which is reported to be as high as 1:150 (World Alliance for Patient Safety - Implementation Manual Surgical Safety Checklist WHO/IER/PSP/2008.05; WHO Guidelines for Safe Surgery 2009 Nov.-Dec.; 23(6): 1105-12). However, despite the lack of resources, the teamwork, communication and leadership still seem to be the important root of adverse events and space for significant improvement.

In pediatric settings, participants of the studies claimed that checklists could cause additional anxiety in adolescence, as well as to be difficult to use in case of emergencies. [12] Secondly, the performed compliance doesn't correlate with the fidelity of checklist implementation, as the reviewed studies reveal. In Levy et al. study, despite 100% completion of pre-incision parts, the items were either not executed as designed in the model, or not performed at all. [16] In Bartz-Kurycki et al. study, checklist was implemented completely between 48-55%. [15]

Most of the studies point out the proper training and introducing the justification of implementation as the ways for further improvements. [8;16] The education seems to be the crucial point in implementation of the surgical safety checklist. In Brasov study in 2015, 40% health care professionals claimed to receive a training in performing the checklist. Staff listed formal training ($p < 0.019$), presentations ($p < 0.004$), and regular audits ($p < 0.019$) as crucial ways of improving compliance of the checklist. [14]

Apart from that, it is suggested that all 3 disciplines (anesthesiology, nursing and surgery) must be present for all phases (including the 7:35 huddle), and the representative of the physician disciplines must be sufficiently experienced [8] The study from Boston also proved the importance of tasks distribution among the team members, which improved the understanding of the teamwork in the operating theaters. [18]

6. CONCLUSIONS

Human error is inevitable, however the improvement of communication between healthcare professionals, standards and rules set by the hospital governance as well as both teaching and audit measures have to be introduced in pediatric surgery settings in order to

provide the best quality patient care. We should always take into consideration the views and perceptions of the patients and their guardians, who hold a significant role in assuring that the preoperative safety measures are being taken.

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