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GUIDELINES

VASCULAR SECTION

Guidelines on the management of abdominal aortic aneurysms: updates from the Italian Society of Vascular and Endovascular Surgery (SICVE)

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ABSTRACT

The objective of these Guidelines was to revise and update the previous 2016 Italian Guidelines on Abdominal Aortic Aneurysm Disease, in accordance with the National Guidelines System (SNLG), to guide every practitioner toward the most correct management pathway for this pathology. The methodology applied in this update was the GRADE-SIGN version methodology, following the instructions of the AGREE quality of reporting checklist as well. The first methodological step was the formulation of clinical questions structured according to the PICO (Population, Intervention, Comparison, Outcome) model according to which the Recommendations were issued. Then, systematic reviews of the Literature were carried out for each PICO question or for homogeneous groups of questions, followed by the selection of the articles and the assessment of the methodological quality for each of them using qualitative checklists. Finally, a Considered Judgment form was filled in for each clinical question, in which the features of the evidence as a whole are assessed to establish the transition from the level of evidence to the direction

and strength of the recommendations. These guidelines outline the correct management of patients with abdominal aortic aneurysm in terms of screening and surveillance. Medical management and indication for surgery are discussed, as well as preoperative assessment regarding patients' background and surgical risk evaluation. Once the indication for surgery has been established, the options for traditional open and endovascular surgery are described and compared, focusing specifically on patients with ruptured abdominal aortic aneurysms as well. Finally, indications for early and late postoperative follow-up are explained. The most recent evidence in the Literature has been able to confirm and possibly modify the previous recommendations updating them, likewise to propose new recommendations on prospectively relevant topics.

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KEY WORDS: Abdominal aortic aneurysm; Vascular surgical procedures; Practice guideline; Systematic review.

These Guidelines were accepted by the Italian National Institute of Health and published in Italian language on 16 September 2021 on the National Guidelines System (https://snlg.iss.it/).

Objectives

When writing these Guidelines, our aim was to review and update the previous 2016 Italian Society of Vascular and Endovascular Surgery (SICVE) Guidelines on Abdominal Aortic Aneurysm (AAA) Disease, in accordance with the instructions of the National Guidelines System (SNLG) Methodological Manual, and to submit them to the Italian National Institute of Health.

The main objective was to outline and provide all stakeholders, General Practitioners, interested medical specialists such as mainly Vascular Surgeons, Angiologists, Radiologists, Cardiologists, Anesthesiologists, patients, family members and caregivers, as well as public decision makers and experts in the field, with the best decision-making processes and diagnostic-therapeutic pathways in case of patients with AAA.

We also believe that the widespread distribution and use of these Guidelines may allow a more targeted use of public resources in the health field as well, favoring and encouraging the most correct and appropriate diagnostic and procedural indications based on Evidence-Based Medicine and on criteria of good clinical practice shared by experts of different backgrounds.

The main objectives of this updated version of the Guidelines are to provide the correct medical and surgical diagnostic and therapeutic background and to provide the main recommendations to be shared between doctor and patient, to be followed to best guide the treatment of the pathology under consideration, as well as to optimize the choice and the diagnostic and therapeutic pathway by personalizing it and establishing it in agreement with the patient, who is to be considered complex due to both the presence of associated comorbidities and the cost-risk-efficacy balance of the surgical procedure.

The following characteristics were also considered: applicability to the national background, openness to the latest findings, proactiveness, dynamicity, flexibility, critical judgment, experts' opinion, clarity for healthcare users and, in a user-friendly version, also for the patient, family member or caregivers.

Methodology

These Guidelines are a review and update of the previous 2016 SICVE Italian Guidelines on AAA Disease.[1] The methodology applied in this update is the GRADE-SIGN version,[2] also referring to the methodological indications contained in the Procedures for the submission and evaluation of Guidelines for publication in the SNLG - Operational Manual[3] and the Methodological Manual for the production of clinical practice guidelines,[4] by the National Center for Clinical Excellence, Quality and Safety of Care (CNEC). The Guidelines were developed according to the AGREE quality of reporting checklist[5] and, once completed, were assessed using the AGREE II tool.[6]

Composition of the working group

The working group was set up as follows: the Guidelines Coordinator; the Scientific Technical Committee, including representatives from each participating Scientific Society; the Panel of Experts - Authors, consisting of a multidisciplinary group of clinicians specialized in the subjects dealt with in these Guidelines; the Methodological Group, with a Reference Methodologist, consisting of experts in systematic Literature review and evaluation of the quality of evidence; the Scientific and Technical Organization Secretariat.

In particular, the multidisciplinary panel included the following specialties: vascular surgery, angiology, anesthesiology, radiodiagnostics and general medicine. In addition

to SICVE, the proposing society, the main scientific societies related to the topics of these Guidelines were involved: Italian Society of Anesthesia Analgesia Resuscitation and Intensive Care (SIAARTI), Italian Society of Angiology and Vascular Pathology (SIAPAV), Italian Society of Medical and Interventional Radiology (SIRM), Italian Interdisciplinary Society for Primary Care (SIICP). To collect the opinions and preferences of patients, the "Titoccotoccati" Vascular Patients Association was also involved. A General Information Sheet on AAA Disease and a short questionnaire on patients' acceptability of the indications proposed by the Guidelines were submitted to "expert patients".

Editorial independence

No external funding has been received for the production of these Guidelines. All authors have declared that they have no financial, professional or other conflicts of interest related to the topics discussed in these Guidelines.

Formulation of clinical questions

The first methodological step was the formulation of clinical questions structured according to the PICO (Population, Intervention, Comparison, Outcome) model according to which the recommendations were issued. The PICO questions were formulated in agreement among the multidisciplinary panel.

Systematic review of the Literature and selection and evaluation process

Then, systematic Literature reviews were carried out for each PICO question or for homogeneous groups of questions. The studies were searched in PubMed, the Cochrane Database of Systematic Reviews (CDSR) and the Cochrane Central Register of Controlled Trials (CENTRAL). The research was carried out from January 2016 onwards, updating the research of the previous SICVE guidelines dating back to December 2015. The systematic review process included the creation of tables containing the research strategies and PRISMA Flow Diagrams for tracking the Literature selection process.

The selection of Literature was carried out independently by pairs of Methodology Group members for each clinical question or topic. The inclusion and exclusion criteria on which the selection was based were established a priori and were based on the elements of the PICO and the study designs. The first selection was based on reading the title and the abstract, while the second selection was based on analyzing the full-text papers. Any assessment disagreements between the two authors were resolved through discussion. Once the final included articles were defined, the authors independently assessed the methodological quality of each article using special qualitative checklists provided by the GRADE-SIGN version methodology. These checklists were used to assess the quality of systematic review/meta-analysis, randomized clinical trials (RCT), cohort studies, case-control studies, and diagnostic accuracy studies. The quality of the case series was evaluated using the checklist of the Institute of Health Economics (IHE),[7] while for the quality of case reports the checklist Case reports guidelines (CARE)[8] was used. Where other international guidelines were used as an evidence base, these were previously assessed using the AGREE II checklist, considering a total score of 60% as the minimum threshold of acceptability (Dimensions 3 and 6: minimum 50%), as indicated in the CNEC Operating Manual.[3]

The levels of evidence attributable to the different study designs assessed by the checklists are shown in Table I.

After assessing the methodological quality of each article included for each PICO question, Evidence Tables were drawn up describing the main characteristics of these studies: study design (for systematic reviews/meta-anal-

TABLE I.—*Levels of evidence.*

Level	Description
1++	High quality meta-analysis and systematic reviews of randomized clinical trials with very low risk of bias; single randomized clinical trials with very low risk of bias
1+	Well-conducted meta-analysis and systematic reviews of randomized clinical trials with low risk of bias; single randomized clinical trials with low risk of bias
1-	Meta-analysis and systematic reviews of randomized clinical trials with high risk of bias; single randomized clinical trials with high risk of bias
2++	High quality systematic reviews, related to case-control or cohort studies; high quality case-control or cohort studies with a very low risk of confounding or bias and a high probability of a causality
2+	Well-conducted case-control or cohort studies with a low risk of confounding or bias and a moderate likelihood of causality
2-	Case-control or cohort studies with a high risk of confounding or bias and a significant risk of non-causality
3	Non-analytical studies, *e.g.* case reports and/or case series
4	Expert opinion

ysis, the number and design of the included studies was indicated), level of evidence, population characteristics (number of patients, pathology, age, sex), intervention(s), comparator(s), outcomes, effect measures for each outcome with their confidence intervals and p-values, any comments regarding methodological limitations and generalizability of the results regarding the PICO question.

From evidence to recommendations

According to the methodology applied, after completing the assessment of the methodological quality of the included articles, the authors then filled in the Considered Judgment form for each clinical question. This form consists of two sections — A and B. The Considered Judgment examines the characteristics of the available evidence (Part A of the form), answering the following questions: 1) how reliable are the studies that contribute to the body of evidence?; 2) are the results of the studies consistent?; 3) are the studies relevant to the target population? 4) Are we sure we have all the available evidence (assessment of possible publication bias)?

Part B of the form was then filled in, supporting authors in moving from the level of evidence to the direction and strength of recommendations. The topics covered in Part B are: 1) benefits-harm balance; 2) acceptability of intervention by patients/relatives/caregivers; 3) applicability/feasibility of intervention in the setting where these Guidelines will be used.

Once the Considered Judgment forms were fully filled in, the Panel of Experts - Authors presented and discussed them during two plenary meetings held by videoconference on 16/02/2021 and 26/02/2021. Following the presentation of the Considered Judgment and recommendations, an informal process for reaching consensus on the strength and direction of the recommendations was carried out.

The recommendations are rated as either strong or conditional. Usually, high-quality evidence from well-conducted studies leads to a strong recommendation; however, it may happen that, when assessing the differences between the population described in the studies and the target population, the acceptability by patients and the applicability of the interventions, the recommendation is issued as "conditional." On the other hand, there may be circumstances where the evidence is technically modest, but there are no negative or controversial aspects of treatment and the clinical importance of the subject is such that a strong recommendation is nonetheless issued. Good Practice Points (GPP) are meant to support the decisions of Guidelines users by providing expert panel "guidance" based on common clinical experience, even if no evidence or insufficient supporting evidence is available, on issues considered relevant to clinical practice. A summary diagram of the degrees of recommendation is shown in Table II.

External review

The final version of the guidelines was sent for external review to independent experts and representatives of patient associations to receive their comments and proposals for amendments or additions. Reviewers were also asked to highlight any facilitating factors and obstacles to the application of the guidelines and suggestions and tools for implementation. The panel took these comments into account, replied to them, and then took advantage of them to implement the text.

Considerations about the applicability of the recommendations

Within the Considered Judgment, the panel expressed some considerations about the applicability of the recommended interventions in the setting where the guidelines will be applied. In particular, the authors considered: the feasibility of the interventions in the entire national setting or only in particularly outstanding centers; the expertise of health professionals required; the financial, health personnel or other resources needed to implement the recommendations. Additional considerations from external reviewers regarding the applicability of the recommendations and suggestions for improving their implementation were received. Considerations about the applicability were considered by the panel during the development of recommendations.

TABLE II.—*Degrees of recommendation.*

Judgment	Recommendation
Undesirable effects clearly outweigh the desirable effects	Strong recommendation against
Undesirable effects are likely to outweigh the desirable effects	Conditional recommendation against
The balance between undesirable and desirable effects is either in strict balance or uncertain	Recommendation for research and limited use in trials
Desirable effects are likely to outweigh the undesirable effects	Conditional recommendation for
Desirable effects clearly outweigh the undesirable effects	Strong recommendation for
Best practice recommended based on clinical experience of the panel	Good Practice Point (GPP)

Reporting

The guidelines were developed following the AGREE quality of reporting checklist.

Results

The studies chosen to update the previous SICVE Guidelines, as well as the studies included to propose new recommendations, are analysed and discussed below. Every possible stage of disease management is discussed, from diagnosis to postoperative follow-up.

Epidemiology, natural history and screening

PICO 1.1 Risk factors

In patients with cardiovascular risk factors (P), does the correction of risk factors (I) compared to non-control (C) reduce the incidence of aneurysm (O)?

The meta-analysis by Kobeissi *et al.* demonstrates that hypertension is associated with an increased risk of developing an AAA with a relative risk of 1.4 for every 20 mmHg of systolic pressure and 2.8 for every 10 mmHg of diastolic pressure.[9] Altobelli *et al.* also confirmed that male population, smoking, high blood pressure, family history and the presence of ischemic heart disease are significantly associated with the risk of AAA, male population and smoking being the most important risk factors.[10] As for smoking habits, Aune *et al.*[11] showed that the relative risk of developing an AAA is 1.87 for those who smoke 10 cigarettes/day and 0.45 for subjects who quit smoking at least 10 years ago. Regarding diabetes mellitus, people with diabetes seem to be at lower risk of developing AAA.[12] It is unclear whether it is diabetes mellitus itself or antidiabetic drugs that provide protection against the development of AAA. Multiple cohort studies have shown that dyslipidemia, metabolic syndrome, chronic renal failure, albuminuria, obesity, abdominal circumference are additional risk factors for AAA, while diabetes was not associated with the risk of AAA in any study.[13-16] The fact that hygiene dietary measures are crucial in preventing the development of AAA is demonstrated by Kaluza *et al.* data on a Swedish population of more than 80,000 subjects, which clearly showed a protective role of a diet with anti-inflammatory characteristics against the development of AAA.[17] Spencer *et al.* did not show a linear association between alcohol intake and risk of developing AAA: there would appear to be a nonlinear correlation with protective effect for low alcohol consumption (< 2 U/day) and an increased risk for high alcohol consumption.[18] The classic cardiovascular risk factors do not appear to be the only risk factors involved in the development of AAA: the prevalence of chronic obstructive pulmonary disease (COPD) was almost double in subjects with AAA compared to those without.[19] Estrogen-progestin therapy does not appear to play a significant role in the development of AAA.[20]

Recommendation

Monitoring risk factors and treating modifiable risk factors is recommended, in particular smoking, high blood pressure, dyslipidemia and obesity, mainly in men over the age of 65 years and in patients with previous cardiovascular disease and/or COPD, to reduce the risk of developing an AAA.

Strong recommendation for (level of evidence 2++)

PICO 1.2 Screening

In the at-risk population (P) should AAA screening (I) be performed rather than not (C) for early detection of aneurysm (O)?

Several meta-analysis assessing the efficacy of screening for AAA with ultrasonography[21-23] clearly showed a reduction in AAA mortality in men over the age of 65 years, but demonstrating inconsistent results on all-cause mortality. Takagi *et al.* also showed the effectiveness of screening in reducing both all-cause mortality and AAA-related mortality in men over the age of 63 years.[24]

The randomized VIVA trial[25] clearly showed a reduction in all-cause mortality in the screened versus unscreened group. This reduction in mortality was likely related to better control of cardiovascular risk factors started after screening for AAA, peripheral arterial occlusive disease and hypertension. However, a randomized clinical trial of the same type carried out in Australia showed no improvement in either all-cause or AAA-related mortality.[26] The same conclusion was reached by the authors of a Swedish cohort study.[27] Two studies that applied mathematical models to the female population to try to predict the impact of AAA screening[28, 29] are particularly interesting, but again the models applied did not demonstrate a real benefit of performing AAA screening in this population.

In conclusion, there is still no clear evidence that AAA screening has an impact on all-cause mortality. In women, screening does not appear to be useful in reducing both all-cause mortality and AAA mortality.[28, 29]

Recommendations

Ultrasound screening for early detection of AAA is recommended in men over the age of 65 years if either smokers, with family history of AAA or suffering high blood pressure.

Strong recommendation for (level of evidence 1+)

Consider ultrasound screening for early detection of AAA in men over the age of 65 years.

Conditional recommendation for (level of evidence 1++)

Consider screening in women over the age of 65 years only if smokers and with family history of AAA.

Conditional recommendation for (level of evidence 1+)

PICO 1.3 Ultrasound diagnosis

In patients at risk for AAA/with cardiovascular risk factors (P) which ultrasonographic diameter should be considered in AAA screening (I, C) to make the diagnosis (O)?

Borgbjerg *et al.*[30] compared the intra- and inter-observer reproducibility of abdominal aortic diameter measurements. "Leading to leading" (LTL: anterior outer to posterior inner) and "inner to inner" (ITI) diameters are preferred over "outer to outer" (OTO) diameter for better reproducibility and better definition of the size of the AAA. The inter-observer reproducibility of three-dimensional ultrasound is better than two-dimensional ultrasound in the diagnosis of AAA; however, this advantage is small.[31] The diameters that seem to prove more reproducibility are the LTL and ITI. Liisberg *et al.* demonstrated a greater sensitivity of non-contrast CT compared to ultrasound in documenting AAA in population screening, but this method is unlikely to be feasible in today's setting due to the costs and the use of radiation.[32] Given the limited evidence, no suggestion can be made for one measurement method over another: the only suggestion is to specify the method used to measure aortic diameter (LTL, ITI, OTO) to provide more complete and reproducible information.

Recommendations

In case of screening for AAA, standard ultrasonographic examination is recommended.

Strong recommendation for (level of evidence 1++)

It is suggested to specify in the ultrasonographic report the method used to measure the diameter of the AAA to ease comparisons at follow-up surveillance: "leading to leading" (LTL), "inner to inner" (ITI), "outer to outer" (OTO) diameter.

Good Practice Point (GPP) recommendation

The "leading to leading" (LTL) and "inner to inner" (ITI) diameters seem to have less intra- and inter-observer variability on ultrasonographic examinations and should therefore be preferred.

Good Practice Point (GPP) recommendation

Surveillance, medical therapy, indication to surgical treatment

PICO 2.1 Surveillance

In patients with AAA without surgical indication (P), is surveillance with Duplex Ultrasonography (I) indicated, and at what intervals, when compared to CT angiography/MR angiography (C), for monitoring growth and prevention of aneurysm rupture (O)?

A meta-analysis and a population study with systematic review emerged from the screening of the Literature. More specifically, Lyttkens *et al.*[33] assessed the quality of life during the surveillance protocol, concluding that surveillance in aneurysms without a current surgical indication is safe and does not impact on patients' quality of life. Soderberg *et al.*[34] assessed the clinical history of aneurysms in the female population: they confirmed the importance of screening in the female population as well, with a large part of AAA requiring repair within 5 years. Sub-aneurysmal lesions (less than 3 cm) developed into aneurysms in 46% of cases during the 5-year follow-up.

Recommendations

Ultrasonographic surveillance should be performed in patients with AAA without surgical indication.

Strong recommendation for (level of evidence 2-)

In patients with AAA without surgical indication, it may be considered to intensify the frequency of ultrasonographic surveillance (or CT angiography, in unclear cases only) at time intervals inversely proportional to aneurysm caliber increase.

Conditional recommendation for (level of evidence 2-)

For aortic aneurysms measuring 3.9 cm or less in diameter, it may be considered to perform surveillance exams no less frequently than every 3 years.

Conditional recommendation for (level of evidence 2-)

For aortic aneurysms without surgical indication measuring between 4 cm and 5.4 cm, a surveillance check may be considered every 6-12 months, contemplating a 3-6-months interval for aneurysms measuring 5 cm or more.

Conditional recommendation for (level of evidence 2-)

PICO 2.2 Medical therapy

In patients with AAA (P), is it recommended to undertake medical therapy (I) as opposed to no therapy (C), to reduce the rate of aneurysm growth and/or the cardiovascular risk (O)?

Medical and behavioral therapy must be implemented effectively from the first surveillance period so that patients have sufficient time to change their lifestyle.

Two recent meta-analysis[35, 36] showed a reduction of AAA growth and rupture risk as well as a reduction of postoperative mortality in patients receiving statin therapy. On the other hand, the FAME-2 Trial showed that the administration of fenofibrate has no effects on AAA growth.[37]

Moreover, further high-quality, longer-term prospective studies are needed to clarify the effects of inhibitors of the renin-angiotensin-aldosterone system on AAA growth, rupture and perioperative mortality.[38-40]

Recommendations

For patients with AAA, who are to be contemplated as affected by polydistrectual arteriopathy, low-dose antiplatelet therapy should be considered, unless a contraindication exists.

Conditional recommendation for (level of evidence 1-)

Statin therapy is recommended to reduce the risk of AAA growth and rupture and postoperative mortality.

Strong recommendation for (level of evidence 1+)

Recommendation for research

Further studies are needed to clarify the effects of antihypertensive drugs on AAA growth and rupture and postoperative mortality.

PICO 2.3 Indication to surgical treatment

In patients with AAA (P) when is surgery (I) indicated compared to medical therapy alone (C) to prevent rupture of the aneurysm (O)?

Currently, the indication for elective treatment of AAAs is based on the aortic diameter. There is global consensus that abdominal fusiform aortic aneurysms of less than 4 cm have a negligible risk of rupture and therefore do not deserve to be surgically treated. It is also well-demonstrated that there is an indication for elective surgical or endovascular intervention for fusiform aneurysms of caliber >5.5 cm in subjects without severe comorbidities, or in saccular-type aneurysms. In the past years there has been much discussion about the indication for treatment of aneurysms with a diameter between 4 and 5.5 cm; in this regard, multicenter randomized studies comparing the results derived from early surgical treatment of aneurysms ranging from 4 to 5.5 cm *versus* clinical surveillance (UKSAT and ADAM trials) led to the recommendation for elective surgery for potential subgroups of patients at increased risk of rupture.

There are few new noteworthy considerations in the recent Literature on the subject. In a 2017 meta-analysis, Ulug *et al.*[41] reported that the morphological feasibility of endovascular aneurysm repair (EVAR) in women is lower than in men (34% *vs.* 54%), and conservative treatment is therefore more often proposed (34% *vs.* 19%). Estimated postoperative mortality is also higher in women than in men, both after open surgery (5.4% *vs.* 2.8%) and endovascular surgery (2.3% *vs*. 1.4%). In their cohort study, Ten Bosch *et al.* stated that in case of symptomatic or suspected symptomatic aneurysms, delayed repair may be justified after 12 hours, after optimization of the patient's clinical status.[42] Soden *et al.* concluded that patients with symptomatic aneurysms have twice the risk of perioperative mortality compared to asymptomatic patients.[43] Therefore, an urgent assessment by the vascular surgeon in case of symptomatic or suspected symptomatic aneurysms is justified.

Recommendations

In case of a fusiform AAA with a diameter greater than or equal to 5.5 cm, elective repair is recommended.

Strong recommendation for (level of evidence 1++)

In case of a fusiform AAA measuring between 5 cm and 5.4 cm in diameter, elective repair should be considered for subgroups of patients at increased risk of rupture, with acceptable surgical risk.

Conditional recommendation for (level of evidence 1-)

Elective AAA repair should be considered if rapid growth of aneurysm size (greater than 1 cm/year) is observed, even if the diameter does not reach 5 cm.

Conditional recommendation for (level of evidence 2+)

In case of a sacciform aortic aneurysm, elective repair may be considered even with diameters smaller than 5 cm.

Conditional recommendation for (level of evidence 2-)

In case of symptomatic (or suspected symptomatic) AAA, urgent assessment by the vascular surgeon should be performed.

Strong recommendation for (level of evidence 2+)

The repair of an isolated iliac aneurysm (common iliac, external iliac, internal iliac, or a combination of these) may be considered if the diameter is greater than 3 cm.

Conditional recommendation for (level of evidence 3)

PICO 2.4 AAA in patients with low life expectancy

In patients with low life expectancy who have AAA >5.5 cm, (P) is medical therapy (I) indicated over surgical treatment (C) to reduce mortality (O)?

AAA patients with severe comorbidities or low life expectancy are often considered unsuitable for surgical treatment, including endovascular treatment. As of today, the only randomized trial evaluating the very long-term survival of fragile AAA patients (greater than 5.5 cm), the EVAR 2 trial,[44] did not show an increase in life expectancy of the latter compared to untreated patients. However, according to this study, endovascular surgical treatment can reduce aneurysm-related very long-term mortality (mean follow-up 12 years). This finding is confirmed by a 2017 meta-analysis[45] even for octogenarian patients where perioperative and mid-term mortality is significantly higher, but still acceptable compared to younger patients. In these patients, endovascular treatment can only be considered appropriate after a complete preoperative assessment, including risk scores measuring a patient's fragility status, such as functional status (predictor of short-term mortality after vascular surgery) or central muscle mass (predictor of long-term survival after EVAR),[46] and after improvement/optimization of their health status. Quality of life also decreases earlier in elderly patients after EVAR and open surgery, with a 4-6 weeks delay in mental health recovery and a 1-3 months delay in physical health recovery compared to younger patients. Yet, after 1 year, quality of life returns to baseline values and, according to the results of a recent systematic review,[47] can be maintained in the long term.

Recommendation

Consider EVAR treatment combined with medical therapy for patients with AAA greater than 5.5 cm with favorable anatomy and low life expectancy, after performing a complete preoperative assessment based on a measurement of the fragility status, even after improvement/optimization of the health conditions.

Conditional recommendation for (level of evidence 1+)

Approach to patients with treatment indication: comorbidity assessment, preoperative investigations, surgical risk

PICO 3.1 Preoperative imaging

In patients with AAA with indication for treatment (P), is CT angiography (I) the best imaging method compared to Duplex Ultrasonography/MR angiography/angiography (C) for proper assessment of the aorto-iliac vascular anatomy and for planning the most appropriate treatment strategy (O)?

No significant studies addressing this clinical question have been published recently. Nevertheless, given the widespread use of the method, the authors decided to issue a recommendation of good clinical practice that is also universally accepted by other international guidelines.

Recommendation

It is suggested the use of CT angiography in patients with AAA with an indication for treatment for the correct assessment of the aorto-iliac vascular anatomy and for planning the most appropriate treatment strategy.

Good Practice Point (GPP) recommendation

PICO 3.2 Perioperative risk assessment and optimisation

In patients with AAA with indication for treatment (P) should routine cardiological assessment (I) be combined with second level examinations (C) for risk stratification of perioperative cardiac events (O)?

All the most recent studies refer to the scheme proposed by the ESC/ESA 2014 guidelines,[48] already adopted to produce the previous 2016 SICVE Guidelines.[1] The meta-analysis by Kalesan *et al.* on the use of preoperative stress testing[49] showed great heterogeneity in the studies and a lack of methodological accuracy, precluding the ability to draw conclusions on whether or not preoperative stress testing offers valuable information for predicting 30-days mortality following surgery. Consequently, this meta-analysis does not support the indiscriminate use of stress testing prior to non-cardiac surgery. We therefore confirm our previous recommendations, confirming the good practice of carrying out second level diagnostic tests only after a careful risk and metabolic capacity stratification.

A small part of the Literature also contains an innovative aspect. The guidelines issued by the Canadian Cardiovascular Society on preoperative risk[50] introduce a new approach to risk stratification, giving more importance to clinical and laboratory stratification and reducing the importance of second level cardiological tests.

New cardiac imaging methods such as coronary CT are also becoming more and more of interest for patient risk stratification, although the results are still very heterogeneous and subject to major methodological limitations.[51]

Recommendations

In the course of preoperative evaluation for AAA, patients should be subjected to a perioperative risk stratification by means of a clinical assessment.

Strong recommendation for (level of evidence 1-)

A cardiological assessment in the preoperative evaluation of AAA patients may be considered.

Conditional recommendation for (level of evidence 2-)

Echocardiographic examination should be performed in the preoperative evaluation of AAA patients when requested by the cardiologist and always in case of either: 1) known or suspected cardiac valvulopathy; 2) known heart disease; 3) previous myocardial infarction; 4) left bundle branch block, 5) cardiac murmur.

Strong recommendation for (level of evidence 2+)

A provocative exercise test in the preoperative assessment of AAA patients with at least two risk factors and reduced functional capacity may be considered according to the cardiological and echocardiographic findings. The indication for coronary angiography is the same as for patients who are not candidates for aortic surgery.

Conditional recommendation for (level of evidence 2-)

Recommendation for research

A part of the Literature introduces new aspects worthy of further investigations by future studies with greater methodological solidity, such as the irrelevance of exercise testing or the use of coronary CT for risk stratification.

PICO 3.3 Renal function

In patients with AAA with an indication for treatment and reduced renal function (P), is preoperative prophylaxis (I) versus no prophylaxis (C) effective in reducing the risk of perioperative renal events (O)?

Patients with kidney failure, diabetes mellitus, congestive heart failure, ejection fraction <40%, arterial hypertension, anemia, advanced age, proteinuria and gout are at increased risk of contrast-induced nephropathy (CIN).[52] There is a linear relationship between the volume of contrast medium administered and the risk of CIN onset and severity. For every 100 mL of contrast infused intraoperatively, there is a 12% increased risk of CIN.[53]

Several strategies are recommended to reduce the risk of kidney injury after EVAR or open surgery. Preoperative hydration is suggested for the prevention of kidney injury, whereas the administration of other substances such as mannitol, antioxidants, fenoldopam, dopamine and antiplatelet drugs have not been proved to protect against the onset of kidney injury. A recent multicenter randomized trial[52] showed that in patients with chronic kidney failure undergoing angiography, the prophylactic administration of sodium bicarbonate does not provide any benefit over saline infusion in reducing the risk of major nephrological adverse events, death or acute kidney injury; furthermore, the prophylactic administration of acetylcysteine does not provide any benefit over placebo in reducing these risks, as confirmed by another randomized trial published in 2008.[54]

Preoperative prophylactic hydration in candidates for AAA surgery is now an established method; hence, the authors agreed to issue a recommendation for good clinical practice.

Recommendation

In patients with AAA with indication for treatment and reduced renal function, preoperative prophylactic hydration is suggested to reduce the risk of pre- and postoperative renal adverse events.

Good Practice Point (GPP) recommendation

PICO 3.4 AAA and synchronous cardiovascular disease: treatment priority

In patients with AAA with an indication for treatment (P), which cardiovascular comorbidity requires corrective treatment prior to/following/combined with AAA repair (I, C) to reduce the risk of perioperative cardiovascular events (O)?

The vascular surgeon is increasingly facing situations where abdominal aortic disease occurs together with other cardiovascular comorbidities. We questioned how to deal with cases in which an AAA occurred concurrently with either a carotid stenosis, heart failure, valvulopathy, coronary artery disease, aortic dissection, thoracic aortic aneurysm, cerebral aneurysm or critical lower limb ischemia.

As regards the association of AAA and acute type B aortic dissection, a multicenter case-series[55] evaluated the possibility to combine the treatment of the two diseases in a single intervention or to postpone it using a "staged" approach; the authors concluded that it was not possible to provide definite answers due to the rarity of associations of such diseases and the scarcity of scientific evidence.

These conclusions are also applicable to the other types of disease association that we set out to investigate. Even though this topic is highly debated in the Literature, no studies of such methodological strength as to be able to point the way forward in such cases were found, and consequently no recommendation could be issued.

PICO 3.5 Standards of structure and team

Does AAA surgery, both open and endovascular, (P) in high-volume centers (more than 30 cases/year) (I) compared to low-volume centers (C) have better (perioperative) mortality and morbidity outcomes (O)?

There is a long-standing body of evidence in the Literature in favor of surgical treatment of several types of complex disease in high-volume center only.[56] National and international case studies have shown that AAAs also appear to benefit from centralized treatment (open or endovascular) to reduce perioperative mortality.[57]

A recent meta-analysis of 16 studies confirmed these advantages in the elective and emergency settings, using both endovascular and surgical techniques.[58] Although the greatest differences are found between the highest-volume centers and the lowest-volume centers, the heterogeneity of the data does not allow a precise limit to be drawn, and further studies are needed to establish such a "cut-off." Although this limit is not homogeneous in the Literature, even the recommendations of the most recent European[59] and American[60] Guidelines have developed a reference data, on which the panel of authors agrees, setting this limit at a minimum of 30 surgeries/year, both open and endovascular, for subrenal AAA disease.

Recommendation

It is suggested to refer patients for surgical treatment of AAA, either open or endovascular, to centers with a high annual operating volume (more than 30 cases/year).

Good Practice Point (GPP) recommendation

Patients' preference

Patients' preference is playing an ever-increasing role in the decision-making processes and in the interaction between the physician and the patient itself regarding treatment pathways to be taken. Some studies in the Literature[61, 62] tried to evaluate patient preferences for treatment strategy when dealing with small aneurysms. There is a clear patient preference for endovascular treatment because of the reduced immediate complication rates and the short postoperative stay and convalescence. However, patients seem to be aware of the long-term risk of failure of the procedure and the need for intense and long-term clinical-instrumental follow-up; this may lead to a partial change in this approach in the future.

To investigate the patient's perspective on the acceptability and clarity of some of the Recommendations proposed, the authors decided to involve a patient association, specifically the "Titoccotoccati" Vascular Patients Association, by submitting to "experienced" patients a General Information Sheet on the disease under investigation and a short Questionnaire with specific Topic Information attached. The questionnaire was given to six "experienced" patients and, in detail, the questions focused on topics such as "Prevention and screening," "Role of the patient in choosing the type of surgical procedure," "Choice of anesthesia," "Postoperative follow-up." The analysis of the answers received showed that:

- the patient is satisfied with the quality and quantity of information contained in the General Information Sheet;
- no patient found the indications proposed in the Guidelines to be "not acceptable";
- the patient is willing to be part of the decision-making process regarding the type of intervention to be performed;
- the preference for the type of surgery, albeit the small sample of patients, showed heterogeneity in the choice.

Open surgical therapy

PICO 4.1 Antiplatelet therapy

In patients who are candidates for non-cardiac surgery (P), does the discontinuation of antiplatelet therapy prior to surgery (I), compared with no discontinuation (C), help to reduce peri- and postoperative (thrombotic/hemorrhagic) complications (O)?

The studies examined several aspects of preoperative discontinuation or continuation of antiplatelet therapy.

In particular, the Lewis *et al.* meta-analysis[63] states that continuing versus discontinuing antiplatelet therapy is likely to make little or no difference in terms of 6-months and 30-days mortality, incidence of bleeding requiring transfusion, incidence of bleeding requiring additional surgery, and incidence of ischemic events (*i.e*. peripheral ischemia, cerebral infarction and myocardial infarction) within 30 days of surgery. Maggard Gibbons *et al.*,[64] and later Childers in an update of the same systematic review,[65] examined additional aspects concerning the management of antiplatelet therapy, such as timing of discontinuation, type of surgery and type of antiplatelet, although they obtained little evidence (no clear difference in outcomes). As regards the patient undergoing dual antiplatelet therapy for a recent coronary procedure and their therapeutic management, compared to the 2016 SICVE Guidelines,[1] the most recent update of international guidelines[66] on the subject was included, which recommends postponing elective

non-cardiac surgery following coronary metallic stenting to at least 30 days and to at least 6 months in case of a medicated stent.

Recommendation

In case of surgery for AAA, continuation of antiplatelet monotherapy with acetylsalicylic acid is suggested; whereas, in regards to thienopyridine therapy discontinuation, it is suggested to decide on a risk-benefit basis for each single case.

Good Practice Point (GPP) recommendation

In case of patients undergoing dual antiplatelet therapy for coronary stenting, it is suggested to postpone surgery for AAA, unless the surgery is urgent, in which case dual antiplatelet therapy can be maintained. In such a scenario, a consensus decision between the relevant healthcare professionals on the risks of surgery and continuation/discontinuation of antiplatelet therapy may be useful.

Good Practice Point (GPP) recommendation

PICO 4.2 Anticoagulant therapy

In patients who are candidates for surgery (P), does the discontinuation of anticoagulant therapy prior to surgery (I), compared with no discontinuation/bridging therapy (C), help to reduce peri- and postoperative complications (O)?

Two systematic reviews with meta-analysis were chosen, both referring to the 2012 Douketis *et al*. Guidelines[67] on perioperative management of antithrombotic therapy. Specifically, Hovaguimian *et al.*[68] examined the population of patients who did or did not discontinue anticoagulant therapy prior to surgery or invasive procedures. Yong *et al.*[69] instead, choosing the same type of population, investigated the efficacy of bridging therapy with heparin after discontinuation of anticoagulant therapy. Both studies highlighted that, prior to surgery, discontinuation of anticoagulant therapy compared with no discontinuation or bridging therapy with heparin guaranteed better outcomes because, with equal thromboembolic risk, the hemorrhagic risk decreased. In particular, in oral anticoagulated patients undergoing surgery, heparin bridging therapy increased the risk of major bleeding and hemorrhagic events, without reducing the risk of perioperative thromboembolism, all-cause mortality, stroke or transient ischemic events compared with no heparin bridging therapy.[69]

However, it is necessary to customize the intervention according to each patient's thromboembolic and hemorrhagic risk. In patients with a mechanical heart valve, atrial fibrillation or a high risk of venous thromboembolism, heparin bridging therapy, rather than no therapy at all, is suggested during the discontinuation of oral anticoagulant therapy.[67]

Recommendation

It is recommended to interrupt anticoagulant therapy prior to open surgery for AAA.

Strong recommendation for (level of evidence 1+)

PICO 4.3 Antibiotic prophylaxis

In patients undergoing surgery for AAA (P) is prophylactic antibiotic therapy (I) effective compared to non-prophylaxis (C) in preventing infection (O)?

The search in the Literature did not highlight any new studies relevant to the proposed clinical question that would modify/update the current recommendation. The previous recommendation is therefore confirmed.

Recommendation

Prophylactic antibiotic therapy should be performed in every patient undergoing AAA surgery.

Strong recommendation for (level of evidence 1-)

PICO 4.4 Deep vein thrombosis prophylaxis

In patients undergoing surgery (P), does the administration of postoperative antithrombotic therapy (I), compared to no administration (C), help to prevent deep vein thrombosis (O)?

The meta-analysis by Pannucci *et al.*[70] stated that routine thromboprophylaxis for every surgical patient carries an unfavorable risk/benefit ratio; therefore, individualized stratification of the risk of venous thrombosis may help to ensure that thromboprophylaxis is only administered to appropriate surgical patients who can benefit from a reduced risk of venous thrombosis without altering possible complications secondary to bleeding. The same authors proposed to use the Caprini Score as a method of stratifying the patient subject to this risk.

The systematic reviews and meta-analyses by Rausa[71] and Felder,[72] on the other hand, examined the differences in the outcomes of patients undergoing conventional (inpatient only) versus prolonged (up to four postoperative weeks) thromboprophylaxis and concluded that prolonged thromboprophylaxis, hence not limited to the in-hospital postoperative stay, reduced the risk of thrombosis. At the

same time, Felder specified that the quality of the evidence was moderate and therefore provided moderate support for the routine use of prolonged thromboprophylaxis, while Rausa suggested that prolonged prophylaxis should only be considered in high-risk patients.[71, 72]

Recommendation for research

There are no studies in the Literature analyzing the application of post-surgical thromboprophylaxis exclusively in patients undergoing AAA surgery. More specific studies looking closely at this population are therefore needed.

PICO 4.5 Anesthesia and pain control

Does the patient undergoing open surgery for AAA (P) benefit from supportive anesthetic techniques (epidural analgesia, continuous infusion of local anesthetics, etc.) (I) compared to using only systemic analgesia with opioids (C) in terms of pain management and clinical outcome (O)?

The search carried out highlighted a Cochrane systematic review[73] comparing epidural analgesia versus opioids. This review shows that: adding epidural to general anesthesia for patients undergoing AAA repair reduces Visual Analogue Scale (VAS) scores and gastrointestinal bleeding; reduces myocardial infarction and postoperative respiratory failure; reduces intensive care unit (ICU) stay; and reduces extubation time. Unfortunately, no reduction in 30-days or in-hospital mortality was highlighted. A review by Qin *et al.*[74] evaluating the transversus abdominis plane block (TAP-Block) technique in comparison with the epidural technique was also selected. Unfortunately, this study has a high risk of bias as different surgical populations with both laparotomy and laparoscopy procedures were examined and various TAP-Block sites were considered. This review suggested that the TAP-Block technique combined with NSAIDs may provide effective dynamic analgesia, no less than epidural infusion in adults after abdominal surgery. However, some limitations have to be considered, such as differences in surgical procedures, TAP-Block position, local anesthetic infusion strategies, NSAIDs protocols, and healthcare professional experience.

Recommendation

It is suggested to consider the utilization of supportive anesthetic techniques for managing the patient undergoing open AAA surgery.

Good Practice Point (GPP) recommendation

PICO 4.6 Post-surgical monitoring

In patients undergoing open surgery for AAA (P), is post-surgical intensive care monitoring (I) necessary compared to the selective use of ICU (C) for the timely detection and treatment of any immediate postoperative complication (O)?

No studies were found that were able to answer the proposed clinical question in terms of numbers and methodology. Nevertheless, the use of a dedicated postoperative monitoring protocol following open surgery for AAA is generally accepted.

In clinical practice, there is a great heterogeneity of postoperative approaches, making comparison difficult. The skills of both the surgical and anesthesiological teams among the various centers are highly variable as well and play a major role.

Recommendation

It is suggested the creation of intra-hospital postoperative routes for patients submitted to open AAA surgery.

Good Practice Point (GPP) recommendation

PICO 4.7 The choice of surgical access

In patients who are candidate for AAA open surgery (P), does the choice of retroperitoneal access (I) compared to the use of transperitoneal access (C) improve the surgical outcomes in terms of perioperative complications (O)?

The selected studies agree that there are no statistically significant differences between the two surgical approaches in terms of mortality, but there are some contradictory results in terms of complication rates (Buck *et al.*[75] report that the transabdominal approach has a higher rate of surgical wound complications than the retroperitoneal approach, while Ma *et al.*[76] state otherwise), bleeding and hospital stay (according to Buck *et al.*[75] the retroperitoneal approach results in higher transfusion rates and longer hospital stays than the transabdominal approach, in disagreement with the review by Ma *et al.*).[76] Deery's cohort study[77] showed that reinterventions and readmissions were higher in cases of transabdominal access (5-year: 42% *vs.* 34%; P<0.01), mainly due to abdominal wall reintervention; Buck[75] also confirmed this finding and demonstrated lower rates of wound dehiscence in retroperitoneal accesses (0.4% *vs.* 2.4%; P=0.045).

As a result, we confirm that there are no consistent data in the Literature demonstrating the predominance of one type of surgical access in open surgery for AAA. Further studies with larger samples and longer follow-up intervals are therefore needed to establish the predominance of one

surgical approach over another, and the criteria in such studies (*e.g.* patient anatomy, surgeon's experience) that lead to the choice of one type of approach over another should be clearly defined.

Recommendation

Consider retroperitoneal access in specific surgical cases (due to anatomy and complexity) taking into account surgeon's experience and expertise in this type of procedure.

Conditional recommendation for (level of evidence 1+)

PICO 4.8 The choice of prosthesis type

In patients undergoing open surgery for AAA (P) does the type of prosthesis used (Dacron/PTFE; medicated/non-medicated) (I, C) result in a higher patency rate, lower prosthetic infection rate and better long-term results (O)?

Our Literature search did not highlight any new relevant studies on the proposed clinical question that could lead to the creation of a recommendation to guide surgeons in the choice of the type of prosthetic material and configuration to be used in case of open surgery for AAA.

PICO 4.9 Intraoperative hemotransfusion and blood salvage

In patients undergoing open surgery for AAA (P), does the use of intraoperative blood salvage (I) compared to non-use (C) reduce the need for homologous blood transfusions during surgery (O)?

No new impactful developments have been reported since the 2016 SICVE document[1] on the use of blood salvage during surgery for AAA; therefore, no new recommendations can be issued.

PICO 4.10 The use of heparin during aortic clamping

In patients undergoing open surgery for AAA (P), does the administration of a weight-optimized dose of heparin (I) compared to a standard dose (C) reduce the risk of aortic and peripheral thrombosis without increasing the hemorrhagic risk (O)?

Our Literature search did not identify any significant studies directly related to the proposed PICO. However, due to the widespread clinical practice and the possible related repercussions, as highlighted by the studies previously chosen for the development of the 2016 SICVE document[1] (no evidence of greater bleeding and better survival, as well as less need for reintervention for complications potentially related to the non-administration of the antithrombotic agent), the administration of a weight-optimized dose of heparin intraoperatively during aortic clamping, also depending on the patient's comorbidities and the extensiveness of aortic reconstruction, is suggested in AAA repair. To make this administration reasonably safe, real-time monitoring of the hemocoagulative profile during the surgical procedure plays an important role.

Recommendation

The administration of a weight-optimized dose of heparin is suggested intraoperatively during aortic clamping in AAA repair.

Good Practice Point (GPP) recommendation

PICO 4.11 The preservation of hypogastric arteries

In patients undergoing open surgery for AAA (P), does the preservation of at least one of the hypogastric arteries (I) compared to non-preservation (C) help to prevent possible early and distant complications (O)?

The cohort study by Marconi *et al.*[78] demonstrated the potential usefulness of hypogastric revascularization in preventing possible complications related to pelvic ischemia induced by the intentional sacrifice of such artery(s). The preservation of the hypogastric artery(s) improves the risk of complications related to its sacrifice; it is reported just one limitation: increased bleeding, also related to the increased complexity of the procedure, but without the latter interfering with operating mortality or major complications.[78] Even though the lack of studies based on adequate research methodology and the small sample size of the PICO population preclude a high-level recommendation, the nature of the effects of the intervention (preservation of the hypogastric artery) makes it possible to issue a good clinical practice recommendation.

Recommendation

In patients undergoing open surgery for AAA, it is suggested the preservation of the vascularity of at least one of the hypogastric arteries to avoid postoperative complications such as intestinal and spinal cord ischemia and erectile disfunction.

Good Practice Point (GPP) recommendation

PICO 4.12 Lower mesenteric artery

In patients undergoing open surgery for AAA (P), does preservation of the inferior mesenteric artery (I) compared to its

ligation (C) help to prevent possible early and distant complications (O)?

Our bibliographic search identified two cohort studies. The two studies are not only qualitatively different in the methodology used but also come to different conclusions: not consistent, not contradictory, but different. The results of the cohort study by Lee *et al.*,[79] superior in methodological quality, allowed us to highlight the non-superiority of preservation of the inferior mesenteric artery over its ligation. Analyzing the cohort study by Jayaraj *et al.*,[80] the only comparative data available from the results reported in the cohort indirectly confirmed the trend highlighted by Lee's study, namely the lower incidence of possible intestinal ischemic complications. The data resulting from the analysis of the two cohort studies make it possible to judge the type of intervention (preservation with re-implantation of the inferior mesenteric artery) as "safe" in terms of mortality and patency of the artery involved despite a longer operating time and a higher rate of complications and/or reinterventions.

Recommendation

In open surgical procedures for AAA, ligation of the inferior mesenteric artery is routinely suggested. Reimplantation instead is suggested in certain specific cases such as: a) obstructive disease of the celiac tripod or superior mesenteric artery; b) suspected intraoperative colic hypoperfusion; c) suspected reduced flow in both internal iliac arteries.

Good Practice Point (GPP) recommendation

PICO 4.13 Management of suprarenal clamping

In patients who are candidates for AAA open surgery with the need for suprarenal clamping (P), does the use of renal protection devices (drugs, renal perfusion with cold solution or specific solution) (I) compared to non-use (C) help to reduce perioperative renal complications (O)?

The Literature review did not provide any studies that would adequately answer this PICO.

Indeed, all the studies initially chosen shared a positive opinion on the use of renal perfusion agents, without, however, having assessed their actual effectiveness in a comparative study between a group with versus without their use. Comparative studies are therefore recommended.

Recommendation for research

In patients who are candidates for open AAA surgery requiring suprarenal clamping, the use of renal protection measures (drugs, renal perfusion with cold solution or specific solution) may be useful for the reduction of perioperative renal complications secondary to ischemic damage. Therefore, comparative studies with a comparison group in which no such measures are used are desirable.

PICO 4.14 "Enhanced recovery after surgery" (ERAS) protocol in aortic surgery

In patients who are candidate for AAA open surgery (P), is the use of the ERAS protocol (I) compared to the standard surgical pathway (C) effective in reducing surgical stress and accelerating postoperative recovery (O)?

In his review, McGinigle selects patients who underwent vascular surgery, analyzing separately the subgroup of the target population of our question (patients treated with open surgery for AAA).[81] Stowers selects patients who underwent abdominal surgery and adopted the ERAS protocol, and among them, he also analyses the subgroup of patients who underwent open surgery for AAA.[82] In the 2014 review, Gurgel concludes that the ERAS protocol and standard management protocols had similar mortality and complication rates in patients who underwent open surgery for AAA.[83] McGinigle, however, in a more recent revision, referring to the same population, reported that the use of the ERAS protocol led to improvements in terms of length of stay, resumption of postoperative diet and ambulation.[81]

The results obtained from the use of the ERAS protocol in aortic surgery are encouraging,[84] but the applicability of this protocol in patients who specifically underwent open surgery for AAA needs further investigation, both with regard to the evaluation of outcomes and medium- and long-term costs.

Recommendation for research

Although the evidence is still limited, there are no negative or controversial aspects regarding the application of the ERAS protocol in patients undergoing open surgery for AAA. The application of such a protocol could therefore be suggested, but further studies are needed.

PICO 4.15 Abdominal closure

In patients who underwent open surgery for AAA through midline incision (P), does the use of prophylactic mesh reinforcement (I) compared to non-use (C) reduce the risk of incisional hernia (O)?

Our Literature search highlighted two well-conducted systematic reviews and meta-analyses[85, 86] reviewing the

same 4 RCTs and therefore the same sample of patients, and showing consistent outcomes: pooled analyses showed that mesh reinforcement significantly reduced the risk of incisional hernia after AAA repair compared to standard suture closure (RR 0.27, 95% CI 0.11-0.66);[86] abdomen closure with a mesh, compared to closure without its use, reduced the risk of incisional hernia (RR 0.24, 95% CI 0.10-0.60).[85]

Indrakusuma reports an increased number of post-surgical seromas in abdominal closure with mesh reinforcement compared to closure with sutures alone, although no mesh infection was reported in any case.[86]

The selected studies seem to be of high quality and to have consistent results; however, it is important to consider the high risk of publication bias due to a completed but unpublished trial and the interference of industry.[86]

Recommendation

In patients considered to be at high risk of incisional hernia, it is suggested the use of mesh reinforcement for abdominal wound closure following open AAA surgery through a midline incision.

Good Practice Point (GPP) recommendation

Recommendation for research

The selected studies analyzed data that did not go beyond 3 years of follow-up after closure of the abdomen with mesh reinforcement; therefore, further studies analyzing long-term results are needed.

Endovascular therapy

PICO 5.1 The choice of anesthesia

Do EVAR candidates (P) who underwent treatment with local/regional anesthesia (I) compared to general anesthesia (C) have a lower incidence of postoperative anesthesiological complications without adversely affecting the outcomes of the procedure (O)?

A recent meta-analysis, produced by Harky *et al.* in 2020 and based on a target population of patients with AAA and indication for elective aortic endoprosthesis repair, showed the advantage of using local or regional anesthesia over general anesthesia.[87]

Limitations of the study were the risk of publication bias and heterogeneity; furthermore, in all the included retrospective studies, the anesthetic method was chosen according to the preferences of the surgeon and anesthetist.

The analysis of the latter study revealed, consistent with the 2016 SICVE document,[1] a benefit in the use of local or regional anesthesia in the population of patients with AAA and who have an indication for aortic endoprosthesis repair in the elective setting. The benefits were: less time spent in surgery, less time spent in hospital, less risk of nosocomial infections and lower costs. However, there were no significant differences between the two methods as regards vascular, cardiac or renal complications or in terms of 30-days mortality.

Recommendation

In patients who are candidates for EVAR it is suggested to consider local or regional anaesthesia in accordance to the clinical and psychological characteristics of the single patient.

Good Practice Point (GPP) recommendation

PICO 5.2 EVAR and instructions for use (IFU)

In patients who are candidate for EVAR (P), based on the anatomical characteristics of the aneurysm, does the use of an endoprosthesis within the IFU (I) compared to use outside the IFU (C) reduce the risk of short- and long-term complications (O)?

We selected three cohort studies,[88-90] performed on target populations comparable to the PICO under investigation, that provided overlapping results and conclusions: compliance with IFU in aortic endoprosthesis implantation in the population of patients with AAA ensures a reduction in the risk of perioperative and distant complications. Failure to comply with IFU leads to an increased risk of endoleak, aneurysmal sac growth >5 mm, reintervention for endoleak, branch occlusion, stent migration, sac rupture, aneurysm-related death. The study by AbuRahma *et al.*[90] found that compliance with IFU is mandatory, while Herman *et al.*[89] stated that if the patient, correctly informed of the risks related to the procedure and of the possible alternative treatments such as open surgery or complex endovascular procedures, still prefers to proceed with standard EVAR, they should be followed up more strictly.

Therefore, although the interpretation of the results and the sample size differed, all three studies showed a worse outcome with treatment outside the IFU.

Recommendation

In case of EVAR, the choice of endoprosthesis model should comply with the IFU. In the case of use outside

the IFU, patients should be informed properly and a strict follow-up program should be performed.

Strong recommendation for (level of evidence 2+)

PICO 5.3 EVAR and hypogastric artery preservation

Do patients with aorto-iliac aneurysm treated with EVAR (P) with preservation of patency of the hypogastric artery (I) compared to patients treated with hypogastric artery occlusion (C) have a lower incidence of pelvic ischemia (O)?

Giosdekos *et al.*[91] highlighted that preservation of patency of the hypogastric artery in the treatment of aorto-iliac aneurysms by iliac branch endoprosthesis is technically feasible with high success rates and low probability of re-intervention. Uni- or bilateral iliac branch endoprosthesis is a safe and effective medium-term solution for the preservation of the pelvic circulation, with high technical success (97.35%), low mortality and gluteal claudication rates (0.67% and 2.15% respectively) and a reintervention rate of 7.78% (average follow-up 16 months).[91] Comparison with previous Literature showed a reduction in the risk of pelvic ischemia correlated to hypogastric occlusion (gluteal claudication 2.15% *vs.* 24% in the series by Verzini *et al.*).[92]

Recommendation

In case of an iliac or aorto-iliac aneurysm to be treated endovascularly, consider iliac branch endoprosthesis implantation when feasible, in order to reduce the risk of pelvic or gluteal complications.

Conditional recommendation for (level of evidence 2++)

PICO 5.4 EVAR and accessory renal arteries

In EVAR candidates with accessory renal arteries (P), does their coverage (I) compared to preservation of the patency of these vessels (C) result in a significant change in the incidence of acute and/or chronic renal complications (O)?

A systematic review considered a population of patients in whom accessory renal arteries had been covered and concluded that this maneuver has the potential to result in renal infarction, but with no significant change in renal function and no increased incidence of mortality, endoleak or reintervention.[93] On the other hand, a cohort study focused on a patient population in which accessory renal arteries were systematically preserved using fenestrated or branched endoprosthesis (F/B-EVAR): preservation of renal arteries and/or accessory renal arteries less than 4 mm in diameter by F/B-EVAR was associated with lower technical success rates, increased operative time, risk of artery damage and kidney loss, higher rates of branch instability and lower rates of primary and secondary patency (study limitations: small sample size and follow-up <12 months).[94] None of these studies directly compared patients who were candidates for endovascular treatment for AAA with accessory renal arteries who underwent renal artery coverage with patients in whom their patency was maintained. Data resulting from the analysis of these studies allow us to confirm a benefit of the proposed intervention (coverage of accessory renal arteries) over their preservation, without any significant negative impact on prognosis or quality of life.

Recommendation

In patients with AAA and accessory renal arteries who are candidates for EVAR, coverage of the accessory renal arteries should be considered whenever necessary to obtain a neck length appropriate to the IFU.

Conditional recommendation for (level of evidence 2+)

PICO 5.5 Juxtarenal AAA

In a patient candidate for high-risk elective open treatment for juxtarenal AAA (P), does treatment with fenestrated endoprosthesis (FEVAR) (I) rather than EVAR and chimney on renal arteries (ChEVAR) (C) result in a different incidence of complications and survival (O)?

An analysis of the studies examined showed that the preferred treatment for juxtarenal aneurysms (JRAA) is endovascular. Of the proposed techniques, although it was not possible to determine a clear benefit of one over the other, FEVAR appeared to have a lower risk of type 1a endoleak, visceral stent occlusion and consequently a lower risk of acute renal failure and dialysis, although it carried higher rates of reintervention and 3c endoleak than ChEVAR.[95, 96] The results of the meta-analysis showed that endovascular treatment of JRAA (FEVAR and ChEVAR) was associated with lower rates of 30-days mortality, acute renal failure, bowel ischaemia and hospital stay than open surgery. It had an increased risk of spinal cord ischemia and reinterventions at 30 days and at a distance. However, due to excessive variability in the duration of follow-up (1 to 7 years in the included studies), no meta-analysis of the results at a distance was performed.[95] Instead, the systematic review assessed that

both endovascular techniques examined are safe and effective. Current evidence does not support routine and extensive use of ChEVAR; however, it does justify it in symptomatic patients at high risk for open surgery, in cases of accidental renal artery coverage during EVAR or in asymptomatic patients who are not candidates for open surgery or FEVAR.[96]

Recommendations

In patients with juxtarenal aneurysms who are candidates for elective EVAR, consider treatment with fenestrated endoprosthesis (FEVAR) rather than chimney (ChEVAR).

Conditional recommendation for (level of evidence 2++)

In patients with juxtarenal aneurysms requiring urgent endovascular treatment or when fenestrated endoprosthesis (FEVAR) is not indicated or available, the use of chimney (ChEVAR) is suggested, preferably restricted to no more than two target vessels.

Good Practice Point (GPP) recommendation

PICO 5.6 EVAR and aortic neck

In a patient with AAA and a short aortic neck at high risk for open treatment (P), does endoprosthesis treatment with transmural fixation systems (I) rather than standard EVAR (C) result in a different incidence of complications and survival (O)?

No studies are available in the Literature that comply with the PICO of interest, hence comparing patients with a hostile neck treated using EVAR with or without transmural fixation systems; both selected studies only consider patients treated with endoanchors (Heli-Fix, Medtronic Vascular, Santa Rosa, CA, USA). Karaolanis *et al.* confirmed that this method is safe and useful in preventing 1a endoleak (6.23% after 6-month follow-up).[97] Qamhawi *et al.*, instead, stated that the placement of endoanchors is technically feasible, safe and useful, with short-term outcomes comparable to the latest generation stent grafts.[98] However, considering the short average follow-up and the lack of randomized trials, they also state that their use in routine clinical practice cannot be recommended.

Recommendation for research

Further studies evaluating the use of transmural fixation systems in combination with EVAR for short-neck AAA are needed.

Ruptured aneurysms

PICO 6.1 Imaging in ruptured AAA

Which imaging method (I/C) is recommended in patients with suspected ruptured AAA (P) for diagnosis (O)?

The review by Sakalihasan *et al.*[99] indicated CT angiography as the diagnostic method used in all EVAR treated cases and in 90% of open treated cases of ruptured AAA. The review conducted by Sever and Rheinboldt[100] clarifies the capabilities of CT angiography in defining the imaging characteristics of a ruptured AAA, aspects compatible with impending rupture and aspects of differential diagnosis with other aortic complications.

The possible limitations of CT angiography are still related to its relative invasiveness and immediate availability.

Recommendation

In patients with clinical/ultrasonographic suspect of rupturing or ruptured AAA, a CT angiography of the thoracoabdominal aorta should be performed on an emergency basis to both confirm the diagnosis and plan the treatment strategy.

Strong recommendation for (level of evidence 2+)

PICO 6.2 Treatment timing

When to treat (I/C) the symptomatic AAA patient with no documented rupture (P) to improve mortality (O)?

The reported data refer to four cohort studies examining the treatment outcomes of symptomatic AAAs.[42, 43, 101, 102] Only two studies consider the outcomes according to the treatment time frame.[42, 43]

None of the reviewed studies showed a significant advantage of emergency treatment over an urgent treatment. These data can be obtained from the two studies mentioned above, that report the day of admission or the 12 hours after presentation as the time limit. In both studies by Chandra *et al.*[101, 102] the time frame between symptoms onset and treatment is generally defined as less than 60 days.

In terms of postoperative mortality/morbidity, the Literature reviewed in this PICO does not document a significant advantage for treating in an emergency setting symptomatic AAAa with no radiological signs of rupture, demonstrating the chance to stabilize and optimize patients' general conditions before submitting them to surgery.

Recommendation

Patients with symptomatic AAA with no documented rupture should be submitted to delayed emergency/urgent intervention, with the possibility of optimizing the patient before surgery.

Strong recommendation for (level of evidence 2+)

PICO 6.3 Permissive hypotension

Does permissive hypotension (I/C) in patients with suspected or confirmed ruptured AAA (P) improve survival and reduce major complications (O)?

A recent Cochrane review[103] does not identify any RCTs comparing controlled hypotension with a normotensive resuscitation strategy. However, it is jointly agreed that maintaining a controlled blood pressure and avoiding fluid overload is considered good clinical practice to reduce bleeding *per se*, avoid consumptive coagulopathy and reduce the incidence of hypothermia. The rationale for applying this management strategy to this population, despite the lack of specific studies, is that hemorrhagic shock resulting from AAA rupture can be compared to that following severe trauma where restrictive fluid therapy is recommended.[104] As there is no absolute definition of "controlled hypotension" it seems reasonable to specify that the target should not be less than 70 mmHg and that it should apply to conscious patients, for whom it is possible to understand whether the perfusion pressure is still adequate. The authors therefore also consider that perioperative hypotension itself was an independent predictor of mortality.[105, 106]

Recommendation

In conscious patients with suspected AAA rupture, it is suggested to achieve and/or maintain a controlled systemic arterial hypotension.

Good Practice Point (GPP) recommendation

PICO 6.4 The surgical choice

In patients with a ruptured AAA (P) which (endovascular/open) treatment (I/C) is recommended to improve mortality and morbidity (O)?

A meta-analysis of 4 randomized trials showed no difference in 30-days mortality between open or EVAR.[107] The other meta-analysis considered, including observational studies and registers in addition to randomized trials, showed a lower 30-days mortality rate for EVAR treatment compared to open treatment,[108] especially in patients over the age of 80 years[109] and including both hemodynamically stable and unstable patients.[110, 111] Unfavorable anatomy for endovascular treatment was a risk factor for mortality in EVAR but not in open,[112] while the number of elective open cases performed in each center affected the mortality of emergency cases.[113] Vascular Quality Initiative registry results showed lower hospital mortality of EVAR patients.[114] Results reported from the IMPROVE trial highlighted similar 30-days mortality rates for open and EVAR, but lower mortality and better quality of life for EVAR patients at 3-years follow-up.[115, 116] In the meta-analysis by Badger *et al.*[107] the 30-day results for EVAR and open are similar in terms of mortality. This finding differs from the results reported by other meta-analysis which included observational studies and registers.[108-114] A large part of the recent Literature reports that EVAR treatment for ruptured AAA results in a survival benefit at 30 days and at follow-up compared to open treatment. EVAR treatment, however, can be applied under specific circumstances of anatomical appropriateness and specific logistical settings that ensure immediate availability of materials.

Recommendation

In case of a ruptured AAA with favorable anatomy for an endovascular treatment, EVAR repair is recommended.

If the anatomy is not favorable for EVAR, open treatment is recommended.

Open treatment is further recommended in emergency cases where EVAR treatment is not logistically feasible.

Strong recommendation for (level of evidence 1+)

PICO 6.5 Compartment syndrome

Is it reasonable to identify and treat intra-abdominal compartment syndrome (I) after surgery for ruptured AAA (P) or not (C) to improve mortality (O)?

The incidence of compartment syndrome varies from 5% to 20% after EVAR or open treatment for ruptured AAA, with no higher incidence after one treatment option than the other.[117-122] There are several risk factors for its onset (anemia, prolonged shock, cardiac arrest, BMI >30 kg/m^2, multiple transfusions, massive fluid infusion, severe hypothermia and acidosis) and the combination of more than one of them increases its occurrence.[117, 119, 120] The onset of compartment syndrome and its treatment are associated with high mortality,[121-123] but decompressive laparotomy reduces its clinical effects.[118, 123-125] Delayed abdominal

closure reduces its incidence, but does not reduce 30-days mortality.[118, 123-125]

The relevant Literature reviewed for this PICO confirmed that the identification of intra-abdominal compartment syndrome is reasonable, as it is associated with a high mortality rate. Once identified, its treatment is justifiable as well.

Recommendation

After open or endovascular surgical treatment for ruptured AAA, the patient should be monitored to identify an eventual abdominal compartment syndrome and possibly treat it with decompressive maneuver.

Strong recommendation for (level of evidence 2+)

Early and remote postoperative controls, late complications

PICO 7.1 Post-EVAR endoleak

In patients with post-EVAR endoleak (P), is early treatment (I) effective compared to monitoring (C) in preventing the risk of AAA rupture (O)?

Our Literature review revealed that the treatment of type 1a endoleak is generally feasible, leading to acceptable medium and long-term outcomes. Many techniques have been described for the treatment of type 1a endoleak. There is no clear evidence in favor of a specific technique.[126] The choice of treatment approach is based on the characteristics of the endoleak, the aortic anatomy and the patient's surgical risk profile. Monitoring should only be applied to selected cases, such as low-flow endoleaks or patients not eligible for open surgery.[127] Studies generally agree that the treatment of type 1a endoleak is feasible and effective. Regarding type 2 endoleak, our Literature review highlighted that it was not a risk factor for rupture per se; however, when combined with other variables, it may be predictive of increased risk of rupture.[128] Specifically, a type 2 endoleak associated with a significant increase in aneurysmal sac is a criterion for considering treatment.[128] The increase in aneurysmal sac can be considered significant when it is greater than or equal to 1 cm, or when it shows a pattern of growth in systematic follow-ups.[128]

Although not all studies agree on the indication for treatment of type 2 endoleak, the relative weight of evidence suggests it should be considered in cases of increased aneurysmal sac.

Recommendations

Early treatment of type 1 and 3 endoleaks is recommended.

Strong recommendation for (level of evidence 1+)

Consider treatment of type 2 endoleaks and endotension provided that there is a pattern of aneurysmal sac growth or an increase in size greater than or equal to 1 cm during follow-up.

Conditional recommendation for (level of evidence 1+)

PICO 7.2 Post-EVAR follow-up

In patients undergoing EVAR (P), does early instrumental monitoring to detect periprocedural complications (I) compared to clinical monitoring alone (C) lead to improved long-term outcomes (O)?

We found considerable heterogeneity in the Literature about follow-up protocols. However, most studies agree on the usefulness of an early follow-up monitoring in guiding further decisions.[129]

Duplex Ultrasonography and contrast-enhanced ultrasound (CEUS) showed good specificity in the diagnosis of endoleak (93% and 95%, respectively); CEUS showed good sensitivity (94%) as well. The latter is therefore suitable for use as an early imaging method as an alternative to CT angiography.[130]

Some evidence seems to support the uselessness of follow-up in reducing mortality. However, this result could be related to the method used and could be overcome with the implementation of CEUS.[131]

Recommendation

In patients who underwent EVAR, consider early instrumental monitoring based on Duplex Ultrasonography/CEUS or CT angiography to guide the following follow-up program.

Conditional recommendation for (level of evidence 1+)

PICO 7.3 CEUS monitoring

In patients undergoing EVAR (P), is CEUS (I) instead of CT angiography (C) equally effective in detecting eventual surgical complications (O)?

Our Literature review showed that CEUS can be used as a safe and effective method for endoleaks detection post EVAR.[132] With respect to the suggestion of using CEUS instead of CT angiography in follow-up after EVAR, there is no unanimous agreement in the Literature.

The quality of available studies was acceptable, but the risk of bias cannot be excluded; these were system-

atic reviews and meta-analysis of non-randomized studies.[129, 130, 132]

Recommendation

Consider CEUS as an alternative or as a complement to CT angiography for endoleak screening after EVAR, especially in cases requiring closer follow-up controls and in patients with kidney failure.

Conditional recommendation for (level of evidence 1+)

PICO 7.4 Post open surgery follow-up

In patients undergoing open treatment for AAA (P) does annual (I) rather than less frequent (C) follow-up improve clinical outcome (O)?

Recent studies showed that follow-up visits could be deferred up to every 5 years without significantly reduce survival.[133] This evidence was based on retrospective studies. On the other hand, there is no unanimous agreement in the Literature on the ideal interval for scheduling follow-ups after open AAA surgery. Therefore, the available Literature does not provide sufficient high-quality evidence to issue strong recommendations.

Recommendation

Follow-up exams with Duplex Ultrasonography or CT angiography are suggested after open surgery for AAA, deferring them at most every five years.

Good Practice Point (GPP) recommendation

Discussion

The systematic screening of the most recent Literature enabled us to question previously issued recommendations and to compare them with the most recent international Guidelines on the subject.[59, 60] In most cases, already existing recommendations were confirmed by the most reliable studies available today and then re-proposed with minor updates, where appropriate. However, some aspects were reassessed.

Regarding ultrasound screening and monitoring, in accordance with the suggestions from the European Guidelines,[59] the authors decided to issue a new recommendation suggesting the need to specify in the report which method of aneurysm diameter measurement was used, making comparisons with further examinations more reliable.

The screening of women for AAA is interesting. European Guidelines do not recommend screening in women unless they are over 50 and have a first-degree relative with AAA;[59] American Guidelines recommend screening in women aged between 65 and 70 years with a history for tobacco use.[60] The Italian Guidelines are in line with the American ones, proposing screening for women over 65 only if they smoke or have a family history of AAA.

Regarding the timing of follow-ups, the analysis of the data allowed us to propose a wider deferral of follow-ups for aneurysms smaller than 3.9 cm in diameter, from the previous checks every 2 years to intervals of no longer than 3 years. Similar approaches are also found in the international panorama.

As life expectancy is gradually improving and surgical techniques are becoming less and less invasive, it is important to assess properly "low life expectancy patients" with an indication for AAA surgery. While the European Guidelines do not recommend any type of treatment for patients defined as having "limited life expectancy"[59], the American Guidelines suggest considering the "Vascular Quality Initiative (VQI) perioperative mortality risk score" in making such decisions.[60] Therefore, for the Italian Guidelines, the authors decided to take into account patients' fragility status when choosing treatment, measuring it by means of specific tests (such as functional status or central muscle mass), even after previous adjustment of health status.

Regarding the assessment of the surgical risk of patients candidate for AAA surgery, the Italian Guidelines propose a recommendation for research regarding a new method of risk stratification by means of coronary CT examination, in order to assess its applicability specifically in patients with AAA, considering the increasingly widespread use and reliability of this method.

The definition of a "high-volume center" for the treatment of AAA was a sensitive and carefully analyzed topic. The data in the Literature relevant to this subject are limited and rather unclear. The American Guidelines recommend the treatment of AAA in centres performing at least 10 EVAR and 10 open surgeries per year;[60] the European Guidelines do not recommend it in centers with a total number of procedures below 20/year.[59] Based on a recent systematic review,[58] the panel decided to set the limit at 30 procedures/year for both EVAR and open surgical treatment and issued a Good Practice Point (GPP) recommendation due to the low level of evidence.

The anesthesiological management of patients undergoing surgery for AAA is constantly evolving. Although it is widely accepted that patients undergoing open surgery for AAA should be monitored intensively, there are no indications in the Literature confirming this approach. The use of new analgesic techniques and management procedures such as the ERAS protocol, as well as the possibility of

sub-intensive or recovery room monitoring, have allowed a selective use of ICUs in recent years. Therefore, new recommendations were produced for the Italian Guidelines concerning the above-mentioned matters, introducing an innovative approach compared to other international guidelines on the subject.[59, 60]

Moreover, compared to the International Guidelines,[59, 60] the Italian Guidelines aimed to shed light on the endovascular surgical approach in patients with juxtarenal aneurysm. New recommendations were issued establishing the superiority of the FEVAR technique over the ChEVAR technique in election, eventually limiting the use of the chimney in emergencies or when a fenestrated endoprosthesis is not available.

The superiority of endovascular treatment of a ruptured AAA is well established when patients' anatomy and center logistics allow it. In this respect, the Italian Guidelines have been updated, in line with the international ones.[59, 60]

The last point assessed was the follow-up program. The authors focused on the need of customizing the follow-up examinations in terms of methods (introducing the possibility to use the CEUS exam) and timing (being more conscious than, for example, the post-EVAR follow-up protocol proposed by the European Guidelines)[59] according to the patient's clinical and anatomical picture.

Conclusions

These Guidelines are intended to outline the most correct management of patients affected by AAA disease, according to the most recent and reliable indications provided by the current Literature, selected following strict methodological criteria of scientific research and selection.

This review highlighted the need to update many existing recommendations over time. It also gave us the chance to examine in depth innovative aspects of the disease currently under investigation, in order to issue new recommendations as well as to provide research ideas for subjects where the scientific evidence is still not solid.

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