Alljärgnevalt täidetakse üksnes see osa, millisele kriteeriumile hinnang antakse.

Meditsiinilise tõenduspõhisuse hinnang

Teenuse nimetus	Septaalharu alkoholablatsioon Rahv.: **TASH** (Transcoronary Ablation of Septal Hypertrophy), **SAA** (Septal Alcohol Ablation)
Taotluse number	1121

1. Meditsiiniline näidustus teenuse osutamiseks;

   Sümptomaatilistel patsientidel Hüpertroofiline Obstruktiivne KardioMüopaatiaga (edaspidi HOCM), kellel vasaku vatsakese väljavoolutrakti obstruktsioon põhjustab vatsakese düsfunktsiooni, mitraalpuudulikkust, müokardi isheemiat või rütmihäireid – on ravi vajalik. Konservatiivse ravi (peamiselt beetablokaatorid) võimaluste ammendumisel on teatud patsientidel näidustatud vaheseina reduktsioon, kas siis kirurgilisel meetodil (transaortaalne müoektoomia) kehavälise vereringe tingimustes või alternattiivina väheminvasiivne septumi alkoholablatsioon. Taotluses märgitud mja asjakohane

   ESC 2014 a. juhiste järgi on septumi redukstioonravi näidustatud NYHA III-IV klassi haigetel, kellel rahuolekugardient LVOT-is on > 50 mmHg. Klass I tõendus C.

2. Tõenduspõhisus

   2.1. kliiniliste uuringute järgi
   multitsentrilised juhulikustatud uuringud puuduvad. Mitmed retrospektiivsed mitmekeskulised uuringud näitavad selekteeritud patsientidel häid tulemusi: NYHA klassi alanemist ja gradiendi reduktsiooni. Varane suremus < 2% on võrreladv kirurgilise raviga. Totaalse AV blokaadi tekke tõenäosus 7-20%. .
   2.2. ravijuhiste järgi;
   ACCF/AHA 2011.
   patsientidel, kes vajavad invasiivteraapiat ja on võimalik ka kirurgiline ravi TASH näidustus klass II tõenduspõhisus B.
   Kirurgilise ravi vastunäidustusel klass II tõenduspõhisus A.

Euroopa Kardioloogide Seltsi juhised

2014 ESC Guidelines on diagnosis and management of hypertrophic cardiomyopathy

There are no randomized trials comparing surgery and septal alcohol ablation (SAA), but several meta-analyses have shown that both procedures improve functional status with a similar procedural mortality.[311–314] Septal alcohol ablation is associated with a higher risk of AV block, requiring permanent pacemaker implantation and larger residual LV outflow tract gradients.[311–314] In contrast to myectomy, most patients develop right-, rather than left bundle branch block after SAA. The risk of AV block following surgery and alcohol ablation is highest in patients with pre-existing conduction disease, and prophylactic permanent pacing before intervention has been advocated.[31]

Soovitused ACCF/AHA juhistest

Recommendations	Class[a]	Level[b]	Ref.[c]
It is recommended that septal reduction therapies be performed by experienced operators, working as part of a multidisciplinary team expert in the management of HCM.	I	C	148,149
Septal reduction therapy to improve symptoms is recommended in patients with a resting or maximum provoked LVOT gradient of ≥50 mm Hg, who are in NYHA functional Class III–IV, despite maximum tolerated medical therapy.	I	B	311–314
Septal reduction therapy should be considered in patients with recurrent exertional syncope caused by a resting or maximum provoked LVOTO gradient ≥50 mm Hg despite optimal medical therapy.	IIa	C	240,316
Septal myectomy, rather than SAA, is recommended in patients with an indication for septal reduction therapy and other lesions requiring surgical intervention (e.g. mitral valve repair/replacement, papillary muscle intervention).	I	C	295
Mitral valve repair or replacement should be considered in symptomatic patients with a resting or maximum provoked LVOTO gradient ≥50 mm Hg and moderate-to-severe mitral regurgitation not caused by SAM of the mitral valve alone.	IIa	C	291–294
Mitral valve repair or replacement may be considered in patients with a resting or maximum provoked LVOTO gradient ≥50 mm Hg and a maximum septal thickness ≤16 mm at the point of the mitral leaflet–septal contact or when there is moderate-to-severe mitral regurgitation following isolated myectomy.	IIb	C	296,317

Uuringud ACCF/AHA juhistest

Data Supplement 2. Invasive Therapies Table

Study Name/Author (Citation)	Aim of Study	Study Design	Study Size	Patient Population	Endpoints	Results	Comments
Usefulness of clinical, echocardiographic, and procedural characteristics to predict outcome after percutaneous transluminal septal myocardial ablation. van der Lee C, et al. (15)	To assess outcomes after septal ablation	Multiple center retrospective review of consecutive pts	131 pts	HCM pts treated with septal ablation	Complications (in-hospital; follow-up); unsuccessful therapy	Ablation success in 90%; complications in 15% including death in 3.8%.	Long-term success was related to procedural volume.
Septal myotomy-myectomy and transcoronary septal alcohol ablation in hypertrophic obstructive cardiomyopathy. A comparison of clinical, haemodynamic and exercise outcomes. Firoozi S, et al. (16)	To compare subjective outcomes among HCM pts undergoing surgical myectomy and septal ablation	Single center retrospective review	44 pts	24 HCM pts treated with surgical myectomy; 20 HCM pts treated with septal ablation	Echocardiographic gradient; NYHA class; cardiopulmonary exercise testing;	Gradient and NYHA improvements were similar between the 2 treatment modalities. Objective exercise parameters improved more with surgical myectomy.	
Long-term effects of surgical septal myectomy on survival in pts with obstructive HCM. Ommen SR, et al. (17)	To determine impact of surgical myectomy on long-term survival	Multiple center retrospective review of concurrent patient cohorts	1337 pts	289 HCM pts treated with surgical myectomy; 228 pts with obstructive HCM treated pharmacologically; 820 nonobstructive HCM pts	Overall and cardiac survival	1, 5, and 10 y survival (98%, 96%, and 83%, respectively) after surgical myectomy is equivalent to healthy age and gender matched population. Overall and cardiac survival superior to that of obstructive pts not offered operation.	30-d mortality = 0.8%. Annualized cardiac mortality rate 0.5% per/y
Hypertrophic obstructive cardiomyopathy: comparison of outcomes after myectomy or alcohol ablation adjusted by propensity score. Ralph-Edwards A, et al. (18)	Review of early outcomes after surgical myectomy or septal ablation	Single center retrospective review of concurrent patient cohorts	150 pts	90 HCM pts treated with surgical myectomy; 60 HCM pts treated with septal ablation	Survival, NYHA class, echocardiographic gradient	Superior 4 y survival, gradient reduction, and NYHA class improvement were observed in the myectomy pts after adjusting for baseline differences.	
Current effectiveness and risks of isolated septal myectomy for hypertrophic obstructive cardiomyopathy. Smedira NG, et al. (19)	To assess effectiveness and risks of surgical myectomy	Single center retrospective review of consecutive pts	323 pts	HCM pts treated with surgical myectomy	Echocardiographic gradient; NYHA class; need for reintervention for HCM	Gradient decreased from 68 mmHg to 17 mmHg ; no in-hospital mortality; freedom from reintervention at 8 y was 92%;	
Outcome of alcohol septal ablation for obstructive HCM. Sorajja P, et al. (20)	Assess outcomes after septal ablation	Single center retrospective review	138 pts	HCM pts treated with septal ablation	Gradient, survival, complications	Relief of LVOT gradient 83% ($p<0.001$); 1.4% procedural death rate with ablation; 4 y overall survival = 88%; 4 y survival free from NYHA class III to IV symptoms was 76% after ablation.	Posthoc Analysis: among pts age <65 y, survival free of symptoms was better with myectomy.
Clinical and echocardiographic determinants of long-term survival after surgical myectomy in obstructive HCM. Woo A, et al. (21)	Determine clinical and echocardiographic factors associated with long-term morbidity and mortality after surgical myectomy	Single center retrospective review of consecutive pts	338 pts	HCM pts treated with surgical myectomy	Mortality, predictors of mortality, NYHA class	Early post-op mortality = 1.5%, 10 y survival = 83+/-3%; Improvement to NYHA class I to II observed in 83%	Predictors of major CV events were age, female sex, preoperative AF, concomitant CABG and preoperative left atrial size
Follow-up of alcohol septal ablation for symptomatic hypertrophic obstructive cardiomyopathy. The Baylor and Medical University of South Carolina experience, 1996 to 2007. Fernandes VL, et al. (22)	Determine long-term outcome after alcohol septal ablation	Retrospective review of consecutive pts	629 pts	HCM pts treated with alcohol septal ablation	Mortality, complications, repeat invasive therapy for HCM pacemaker requirement, and NYHA class	Early mortality = 1%, 1, 5, 8 y survival (97%, 92%, 89%, respectively), Permanent pacemaker required in 8.2%. Mean NYHA class at 4-5 y decreased from 2.8 +/- 0.6 to 1.2 +/--0.5 ($p<0.001$) = 1.2	
Transcoronary ablation of septal hypertrophy for hypertrophic obstructive cardiomyopathy: feasibility, clinical benefit, and short term results in elderly pts. Gietzen FH, et al. (23)	Evaluate symptomatic and hemodynamic results of septal ablation in elderly pts	Single center retrospective review of consecutive pts	157 pts	HCM pts treated with septal ablation. Group I agae <60 y, Group II age ≥60 y.	Mortality, gradient, complications, NYHA class	Early mortality similar between groups. Total mortality 3.8% in Group I vs. 9.1% in Group II. Similar improvement in symptoms and exercise time. Pts age ≥60 y more likely to have persistent atrioventricular heart block (5% vs. 17%, $p=0.015$. NYHA class improved from 2.7 to 1.4 in Group I and 3.0 to 1.7 in Group II.	

Survival after transcoronary ablation of septal hypertrophy in hypertrophic obstructive cardiomyopathy (TASH): a 10 year experience. Kuhn H, et al. (24)	Determine impact of septal ablation on survival	Single center retrospective review of consecutive pts	644 pts	HCM pts treated with septal ablation	Mortality (early and late)	Early mortality = 1.2%, annual mortality = 3.2% per/ y	Early and late mortality improved after converting to low alcohol dosing
Long-Term Outcomes in High-Risk Symptomatic Pts With HCM Undergoing Alcohol Septal Ablation. Kwon DH, et al. (25)	Assess outcomes after septal ablation in high-risk pts	Single center retrospective review	55 pts	HCM pts at high risk for cardiac surgery treated with septal ablation	Gradient, quality of life, NYHA class, mortality	Gradient and quality of life improved at 3 mo and sustained through 1 y. Reduction in number of pts with NYHA class ≥3 (93% NYHA class >2). Early mortality = 2%, 1, 5, 10 y survival (96%, 87%, 76%)	
Comparison of ethanol septal reduction therapy with surgical myectomy for the treatment of hypertrophic obstructive cardiomyopathy. Nagueh SF, et al. (26)	Compare hemodynamic efficacy of surgical myectomy and septal ablation	Multicenter retrospective case-control comparison	82 pts	41 HCM pts treated with septal ablation; 41 age and gradient matched HCM pts treated with surgical myectomy	Gradient, NYHA class, exercise capacity	At 1 y after procedure, improvements in gradient, symptoms and exercise capacity were similar between the 2 groups	
Outcome of pts with hypertrophic obstructive cardiomyopathy after percutaneous transluminal septal myocardial ablation and septal myectomy surgery. Qin JX, et al. (27)	Evaluate results of surgical myectomy as compared to septal ablation	Single center retrospective review	51 pts	25 HCM pts treated with septal ablation; 26 HCM pts treated with surgical myectomy	Gradient, NYHA class	Gradient reduction more robust with surgery; NYHA improvements similar	Ablation pts in this study were on average 15 y older than myectomy pts
Updated meta-analysis of septal alcohol ablating versus myectomy for HCM. Agarwal S, et al. (28)	Compare outcomes of HCM pts undergoing surgical myectomy with septal ablation	Meta-analysis	12 published studies	HCM pts treated with either surgical myectomy or septal ablation	Mortality, complications, NYHA class, gradient	No differences in mortality, NYHA class, ventricular arrhythmia, or need for reintervention. Ablation pts had higher residual gradient and rate of advanced conduction abnormalities.	

2.2 oodatavad ravitulemused, sealhulgas ravi tulemuslikkuse lühi- ja pikaajaline prognoos; võrdlus hinnangu punktis 2.1. esitatud alternatiividega;

Hästi valitud patsientidel hea kogemusega keskuses on saavutatav elulemuse paranemine, oluline gradiendi langus ja südamepuudulikkuse vähenemine. HOCM on surmapõhjusena tõenäoline ja protseduur kõrvaldab vasaku vatsakese obtruktsiooni, vältides koormusel tekkivaid sünkoope ja äkksurmaohtu. Paraneb nii elukvaliteet, kui ka tüsistuste tekkesagedus.

2.3. ravi võimalikud kõrvaltoimed;

suremus ca 1% (tüsistunud protseduur), ulatuslik infarkt, trifastsikulaarne blokaad, AV ülejuhtehäired ja südame tehisrütmuri vajadus. Totaallse atrioventrikulaarse blokaadi ja seega ka tehisrütmuri implanteerimise võimalikkus on 7-20%

2.4. teenuse kohaldamise tingimuste vajalikkus;

vajalikud spetsialiseeritud angiograafiakeskused, probleemiga süvitsi tegelevad kardioloogid ja invasiivkardioloogid. Taotluses esitatud 10 ravijuhtu aastas on pigem antud varuga.

3. Eestis kasutatavad alternatiivsed raviviisid;

Kirurgiline müektoomia/müotoomia on traumaatiline kardiokirurgiline operatsioon kehavälise vereringega. Kogemus on seni väga väike ja minu hinnangul on kirurgiline radikaalsus (eemaldatava vaheseinaosa suurus) olnud seni tagasihoidlik. Võrreldes suure kirurgilise operatsiooniga on taotletav teenus tuntavalt väheminvasiivne ja kergemini talutav, rehabilitatsiooniaeg lühem. Suremus on kirjanduse andmetel siiski mõlemalprotseduuril võrdne; s.o. < 2%.

4. Tõenduspõhisus Euroopas aktsepteeritud ravijuhendite alusel;

Vaata punkt 2. Suured juhulikustatud uuringud puuduvad. Andmed baseeruvad retrospektiivsel analüüsil, kuid peamiselt kirurgilise ravi ja alkoholablatsiooni võrdluses.

Ei seata kahtluse alla septaalse reduktsiooni vajadust sümptomaatilistel haigetel, kellel konservatiivne ravi on end ammendanud.

5. Kogemus maailmapraktikas ja Eestis;

   Meetod juurutati 1995 a. Saksamaal ja uuringutes on näidatud ühes keskuses ravitud haigeid tavaliselt üle 100.

   Eestis alustasime 2009 a. ja hetkel on Tartus ravitud antud meetodil 7 haiget (1 haige aastas!) ja PERH-is umbes samapalju.

6. Teenuse tegevuse kirjeldus;

   Vajalik on põhjalik eelnev uuring, mis ei johtu mitte TASH protseduurist vaid haigusest (geneetika, EKG, koormusEKG, ehhokardioskoopia ja vajadusel TEE ning ka magnetuuring).

   Protseduuri läbiviimine toimub angiograafiakabinetis üldnarkoosis transösofagiaalse ehhokardioskoopia kontrolli all ja kujutab endast sarnast protseduuri koronaarangioplastikaga. Vahe on selles, et ühel juhul soon laiendatakse/avatakse, TASH protseduuri ajal aga koronaararteri septaalharu ja kapilaaristik okluseeritakse kas absoluutse alkoholi või mikropartiklite abil. Sõnaga: kutsutakse tahtlikult esile hüpertroofilise vaheseina segmentaarne infarkt, mis viib vaheseina reduktsioonini (tekib arm) ja seega ka obstruktsiooni leevenemise või kadumiseni.

   Ajakulu on suurem kui koronaarangioplastika puhul. Vahendite kulu aga koronaarstendi võrra väiksem.

   Tehniliselt:

   Ca 2-3 tundi, 2arsti, lisaks üks kardioloog TEE ja üks anestesioloog , 3 õde, 1 hooldaja

   Diagnostiline koronarograafia, juhtekateeter, 300 cm koronaarjuhtetraat, 1-3 koronaarballooni, ehhokontrastaine, 1 ampull absoluutset alkoholi, paremasse vatsakesse ajutine kardiostimulaatori elektrood kaheks päevaks, intensiivravi ca 2 päeva.

7. Eestis teenust vajavate patsientide arvu hinnang ja prognoos;

Patsientide selektsioon peab olema väga täpne ja näidustus kriitilise pilguga üle vaadatud. Seega pakun 1 milj. elaniku kohta maksimaalselt 5-7 protseduuri aastas.

8. Patsiendi isikupära võimalik mõju ravi tulemustele;

Puudub: kuid patsiendil peab olema võimalus septaalse reduktsiooni näidustuse korral võimalus valida alkoholablatsiooni ja kirurgilise ravi vahel.

9. Teenuse pakkuja valmisoleku, sealhulgas vajalikud meditsiiniseadmed ja personali kvalifikatsioon ning pädevus, võimalik mõju ravi tulemustele;
   9.1. teenuse osutaja;
   Eestis peaks tegevuse piirama kahe keskusega: üks Tartu angiograafias ja teine Tallinnas (hetkel PERH) ja ka protseduuri teostavaid arste saaks olla vaid kaks.
   9.2. infrastruktuur, tervishoiuteenuse osutaja täiendavate osakondade/teenistuste olemasolu vajadus; pole vajadust. Olemasolevad angiograafiakabinetid ja varustus on protseduuriks piisavad.
   9.3. personali täiendava väljaõppe vajadus;
   väljaõpe on SA TÜK-is ja PERH-is olemas. Jooksev täiendamine on iseenesest mõistetav.

9.4. minimaalsed teenuse osutamise mahud kvaliteetse teenuse osutamise tagamiseks;
heal taseme kindlustamiseks oleks vaja teostada keskuses aastas ca 10 protseduuri.
9.5. teenuse osutaja valmisoleku võimalik mõju ravi tulemustele;
valmisolek on olemas ja protseduure tehakse aastast 2009.

10. Teenuse seos kehtiva loeteluga, sealhulgas uue teenuse asendav või täiendav mõju kehtivale loetelule;

    Kuna teenus on tehnilisest küljest väga sarnane koronaarangioplastikaga, siis täiendavaid rahalisi vajadusi ei teki; korrastub aga statistika, sest koodi 7655 (koronaarangioplastika) jääb vähemaks.

11. Teenuse osutamiseks vajalike tegevuste kirjelduse asjakohasus ja õigsus

Protseduur on kirjeldatud lakooniliselt, kuid sisuliselt õigesti. Teenuse nimetus võiks aga olla: müokardi septumi alkoholablatsioon (sest eesmärk ei ole mitte septaalharu sulgemine, vaid septumi osalise nekroosi esilekutsumine)

12. Kokkuvõte

	Vastus	**Selgitused**
Teenuse nimetus	*Septaalharu alkoholablatsioon*	*Müokardi septumi ablatsioon (ei pea tingimata kasutama alkoholi, eesmärk on septumi ablatsioon, mitte septaalharu)*
Ettepaneku esitaja	EKS	
Teenuse tõenduspõhisus taotluses esitatud näidustustel võrreldes alternatiivi(de)ga	***IIA ja IIB***	
Senine praktika Eestis	Ca 15 haiget	
Vajadus	Maks. 10 haiget aastas+	+
Muud asjaolud	+	+
Kohaldamise tingimuste lisamine	Pole vaja	

13. Kasutatud kirjandus

Juhistest

9.1.3 Invasive treatment of left ventricular outflow tract obstruction

There are no data to support the use of invasive procedures to reduce LV outflow obstruction in asymptomatic patients, regardless of its severity.

Invasive treatment to reduce LVOTO should be considered in patients with an LVOTO gradient ≥50 mm Hg, moderate-to-severe symptoms (New York Heart Association (NYHA) functional Class III–IV) and/or recurrent exertional syncope in spite of maximally tolerated drug therapy. In some centres, invasive therapy is also considered in patients with mild symptoms (NYHA Class II) who have a resting or maximum provoked gradient of ≥50 mm Hg (exercise or Valsalva) and moderate-to-severe SAM related mitral regurgitation, AF, or moderate-to-severe left atrial dilation but there are few data supporting this practice.[277]

9.1.3.1 Surgery

The most commonly performed surgical procedure used to treat LVOTO is ventricular septal myectomy (Morrow procedure), in which a rectangular trough that extends distally to beyond the point of the mitral leaflet–septal contact is created in the basal septum below the aortic valve.[278] This abolishes or substantially reduces LV outflow tract gradients in over 90% of cases, reduces SAM-related mitral regurgitation, and improves exercise capacity and symptoms. Long-term symptomatic benefit is achieved in 70–80% of patients with a long-term survival comparable to that of the general population.[279–287] Pre-operative determinants of a good long-term outcome are age <50 years, left atrial size <46 mm, absence of atrial fibrillation and male gender.[287]

The main surgical complications are AV nodal block, ventricular septal defect and aortic regurgitation (AR), but these are uncommon in experienced centres using intraoperative TOE guidance.[286,288,289] When there is co-existing mid-cavity obstruction, the standard myectomy can be extended distally into the mid-ventricle around the base of the papillary muscles, but data on the efficacy and long-term outcomes of this approach are limited.[290]

Concomitant mitral valve surgery is required in 11–20% of patients undergoing myectomy.[114] In patients with marked mitral leaflet elongation and/or moderate-to-severe mitral regurgitation, septal myectomy can be combined with one of several adjunctive procedures, including mitral valve replacement, posterior-superior realignment of the papillary muscles, partial excision and mobilization of papillary muscles, anterior mitral leaflet plication, and anterior leaflet extension using a glutaraldehyde-treated pericardial patch that stiffens the mid-portion of the leaflet.[291–294] An elongated anterior mitral leaflet favours mitral valve repair instead of replacement.[295] Surgical mortality for myectomy with mitral intervention is around 3–4%.[294,296,297]

9.1.3.2 Septal alcohol ablation

In experienced centres, selective injection of alcohol into a septal perforator artery (or sometimes other branches of the left anterior descending coronary artery) to create a localized septal scar has outcomes similar to surgery in terms of gradient reduction, symptom improvement and exercise capacity.[298–302] The main non-fatal complication is AV block in 7–20% of patients and the procedural mortality is similar to isolated myectomy.[299–303]

Due to the variability of the septal blood supply, myocardial contrast echocardiography is essential prior to alcohol injection. If the contrast agent cannot be localized exclusively to the

basal septum at and adjacent to the point of mitral-septal contact, the procedure should be abandoned.[111–113]

Injection of large volumes of alcohol in multiple septal branches—with the aim of gradient reduction in the catheter laboratory—is not recommended, as it is associated with a high risk of complications and arrhythmic events.[304]

Alternative methods have been reported in small numbers of patients, including non-alcohol septal embolisation techniques (coils,[305,306] polyvinyl alcohol foam particles,[307] cyanoacrylate[308]) and direct endocavitary ablation (radiofrequency, cryotherapy).[309,310] These alternative methods have not been directly compared with other septal reduction therapies and long-term outcome/safety data are not available.

9.1.3.3 Surgery vs. alcohol ablation

There are no randomized trials comparing surgery and septal alcohol ablation (SAA), but several meta-analyses have shown that both procedures improve functional status with a similar procedural mortality.[311–314] Septal alcohol ablation is associated with a higher risk of AV block, requiring permanent pacemaker implantation and larger residual LV outflow tract gradients.[311–314] In contrast to myectomy, most patients develop right-, rather than left bundle branch block after SAA. The risk of AV block following surgery and alcohol ablation is highest in patients with pre-existing conduction disease, and prophylactic permanent pacing before intervention has been advocated.[315]

The operative mortality of septal myectomy in children is <2% in experienced centres.[288] Recurrence of LVOTO requiring re-operation is rare, except in infants and neonates, due to technical limitations of resection and progression of myocardial hypertrophy. Septal alcohol ablation is controversial in children, adolescents and young adults because there are no long-term data on the late effects of a myocardial scar in these groups, and because the technical difficulties and potential hazards of the procedure in smaller children and infants are greater.

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