Meniscal procedures are not increased with delayed ACL reconstruction and rehabilitation: results from a randomised controlled trial

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ABSTRACT

Objective To assess whether initial non-operative treatment of anterior cruciate ligament (ACL) ruptures with optional delayed ACL reconstruction leads to more meniscal procedures compared with early ACL reconstruction during the 2-year follow-up.

Methods We compared the number of meniscal procedures of 167 patients with an ACL rupture, who either received early ACL reconstruction (n=85) or rehabilitation therapy plus optional delayed ACL reconstruction (n=82), participating in the Conservative vs Operative Methods for Patients with ACL Rupture Evaluation trial. Patients were aged 18 to 65 years (mean 31.3, SD 10.5), 60% male sex (n=100). We evaluated the presence and location of meniscal tears by baseline MRI. We analysed and compared how many patients per randomisation group had a meniscal procedure during follow-up in the ACL injured knee, adjusted for sex, body mass index, age group and orthopaedic surgeon.

Results At baseline, 41% of the entire study population (69/167 patients) had a meniscal tear on MRI. During the 2-year follow-up, 25 patients randomised to early ACL reconstruction (29%, 25/85 patients) had a meniscal procedure, compared with 17 patients randomised to rehabilitation plus optional delayed reconstruction (21%, 17/82 patients) (risk ratio 0.67 with 95% CI 0.40 to 1.12, p=0.12). Of these patients who received early ACL reconstruction (n=82) and patients that received delayed ACL reconstruction (n=41), 5% of the patients had an additional isolated meniscal procedure after ACL reconstruction. In patients who received no ACL reconstruction (n=41), 10% (n=4) had an isolated surgical procedure for a meniscal tear during the 2-year follow-up period.

Conclusion Initial non-surgical treatment of ACL ruptures followed by optional delayed ACL reconstruction does not lead to a higher number of meniscal procedures compared with early ACL reconstruction over a 2-year follow-up period.

Trial registration number NL 2618.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ It is thought that persistent instability in patients with an anterior cruciate ligament (ACL) deficient knee increases the risk of additional meniscal injuries. The existing evidence is too weak to conclude that non-operative treatment of ACL ruptures leads to more new meniscal tears compared with surgical treatment.

WHAT THIS STUDY ADDS

⇒ The number of meniscal procedures in patients with an ACL rupture who were treated with rehabilitation therapy and optional delayed ACL reconstruction does not differ from patients who received early ACL reconstruction.

⇒ After ACL reconstruction, in both treatment groups no new meniscal procedures were performed in parts of the meniscus other than the area that was already damaged as seen during ACL reconstruction.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Results from this study suggest that starting non-operative treatment in patients with an ACL rupture does not to lead to more meniscal procedures. This is of value for guidelines and shared decision making in the treatment of ACL ruptures.

INTRODUCTION

Meniscal injury influences the fate of a traumatic knee significantly and complicates the recovery of the anterior cruciate ligament (ACL) injured knee. An ACL rupture has a high chance of concomitant meniscal injury which varies in different studies from 40% to 60%.[1–6] Patients with both an ACL rupture and a meniscal tear have a sixfold increased risk for osteoarthritis of the knee, with the meniscal injury as the most contributing risk factor.[7] Furthermore, meniscal injuries associated with ACL ruptures can lead to additional complaints such as locking knee, limited range of motion, pain, swelling and often require physiotherapy or surgical intervention.[8 9]

It is thought that persistent instability in patients with an ACL deficient knee increases the risk of additional meniscal injuries.[10] One of the reasons to perform ACL reconstructions shortly after trauma is to reduce instability and also to reduce the risk of new meniscal injuries. A recent systematic review showed that the existing evidence is too weak to conclude that non-operative treatment of ACL ruptures leads to more new meniscal tears compared with surgical treatment.[11] However, an exploratory analysis of the KANON trial suggested that early ACL reconstruction may reduce the risk of new medial meniscal damage after an ACL rupture.[12]

Since previous data, except the KANON trial, are not from randomised trials, they are not optimal to address the risk of additional meniscal injuries

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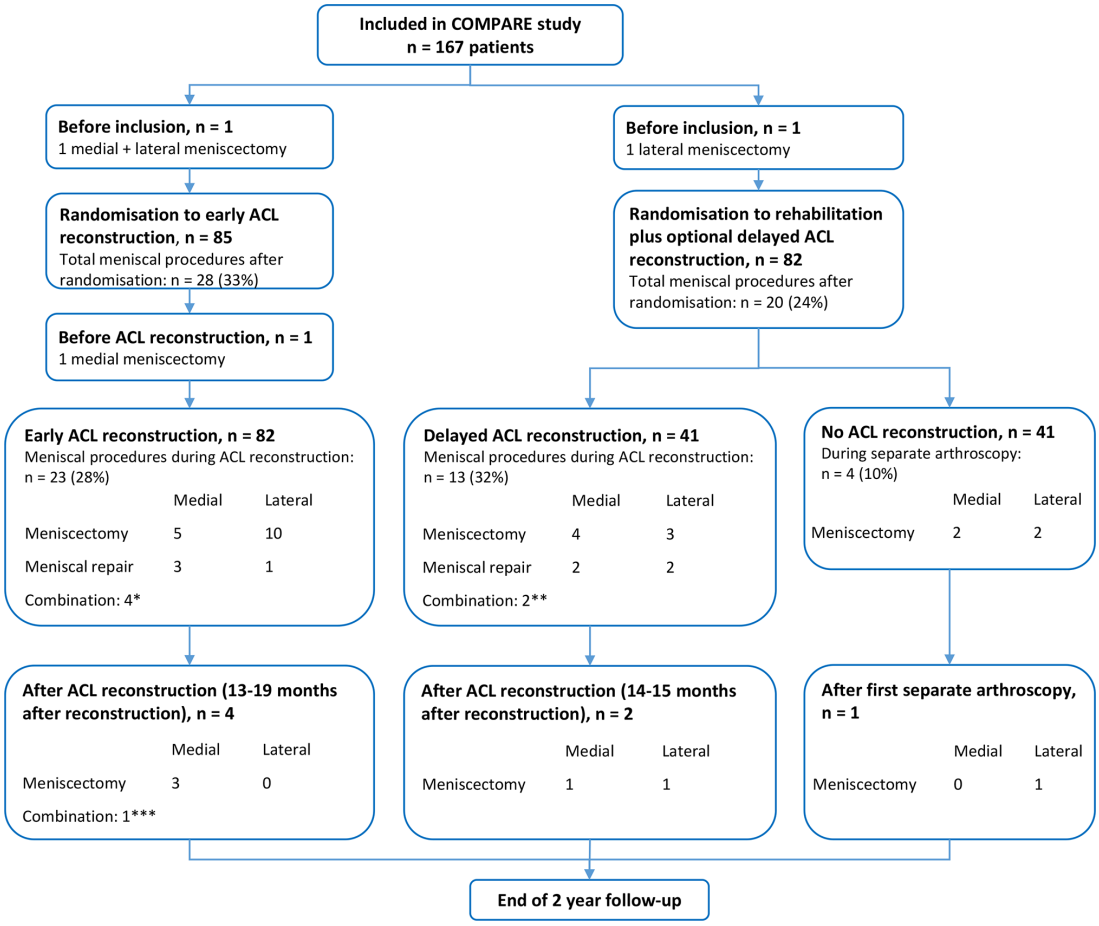

Figure 1 Meniscal procedures during follow-up. *2 medial meniscectomy+lateral meniscectomy, 1 medial meniscal repair+lateral meniscectomy, 1 lateral meniscal repair+lateral meniscectomy. ** 1 medial meniscal repair+lateral meniscal repair, 1 medial meniscal repair+lateral meniscectomy. *** 1 medial meniscectomy+lateral meniscectomy. ACL, anterior cruciate ligament.

with non-operative treatment of ACL ruptures. Therefore, we compared the number of meniscal procedures in a secondary analysis of the most recent and largest randomised controlled trial (RCT) that compared two different treatment strategies for ACL rupture: early ACL reconstruction compared with rehabilitation therapy plus optional delayed ACL reconstruction in case of persisting instability complaints or the inability to reach a desired activity level.[13] Our aim was to evaluate whether initial non-operative treatment of ACL ruptures, followed by optional delayed ACL reconstruction leads to more meniscal procedures compared with early ACL reconstruction during a 2-year follow-up.

METHODS

Study design and patients

Data from the Conservative vs Operative Methods for Patients with ACL Rupture Evaluation (COMPARE) trial were used.[13] This is a multicentre RCT that recruited patients with an acute ACL rupture at six hospitals in the Netherlands. Patients aged 18–65 year with an acute complete primary ACL rupture (within 2 months after the initial trauma) confirmed by MRI and physical examination were included. Exclusion criteria were history of ACL injury of the contralateral knee, a dislocated bucket handle lesion of the meniscus with an extension deficit, presence of another disorder that affects the activity level of the lower limb or insufficient command of the Dutch language.

Informed consent was obtained from each patient in the study. After informed consent was obtained and baseline measurements had been carried out, patients were randomised into one of the two treatment groups. Randomisation was central, using computer generated randomisation lists (block randomisation, with variable sizes of the blocks (2, 4 and 6), stratified by orthopaedic surgeon and age group (<30 and ≥30)).

Patient involvement

In the absence of an adequate patient association, we formed a panel of patients with rupture of the ACL to review and comment on our study. Our patient panel consisted of three patients with an ACL rupture. The trial setup was discussed with the patient panel before the subsidy request was submitted. In collaboration with these patients, we templated our study protocol as much as possible to our routine follow-up periods and standard measurements. Since 2010, we have expanded our use of patient participation panels on a regular basis. We plan to disseminate the results of the study to the study participants.

Interventions

Patients were randomly assigned to early ACL reconstruction or initial rehabilitation therapy plus optional delayed ACL reconstruction. Patients randomised to early ACL reconstruction received ACL reconstruction within 6 weeks after randomisation. Following surgery, patients were referred to physical

Table 1 Baseline characteristics

	Early ACL Reconstruction (n=85)	Rehabilitation plus optional delayed ACL reconstruction (n=82)
Age at inclusion, years	31.2 (10.3)	31.4 (10.7)
Male sex, n (%)	49 (57.6)	51 (62.2)
BMI (kg/m^2)	24.3 (3.7)	25.0 (4.1)
Tegner preinjury	7.0 (2.3)	7.1 (2.0)
Time between trauma and inclusion, days	38.0 (14.5)	41.0 (14.0)
ACL injured during sport, n (%)	76 (89.4)	71 (86.6)
Lachman positive, n (%)	85 (100.0)	82 (100.0)
Meniscal injury on baseline MRI*		
No meniscal injury, n (%)	50 (58.8)	47 (57.3)
Meniscal tear, n (%)	34 (40.0)	35 (42.7)
Medial meniscus	14 (16.5)	16 (19.5)
Lateral meniscus	11 (12.9)	9 (11.0)
Both	9 (10.6)	10 (12.2)

Data are presented as mean, with SD in brackets, unless otherwise reported.
*1 missing in early ACL reconstruction.
ACL, anterior cruciate ligament; BMI, body mass index.

therapy for further rehabilitation, according to the Dutch ACL guideline.[14] Depending on the findings during the arthroscopy, meniscal surgery was performed during the ACL reconstruction. Patients randomly assigned to rehabilitation therapy started with a minimum of 3 months supervised physical therapy, also following the Dutch ACL guideline.[14] Exercises were focused on balance and proprioception. MRI findings were explained and if a symptomatic meniscal tear existed, arthroscopic meniscectomy or repair could be performed. After the period of rehabilitation therapy, patients could opt for an ACL reconstruction, in case of persistent instability complaints or the inability to reach a desired activity level, in consultation with the orthopaedic surgeon.

In total, 167 patients were included and randomised, 85 in the early ACL reconstruction group and 82 in the rehabilitation therapy plus optional delayed ACL reconstruction group. Of the latter 41 patients received a delayed ACL reconstruction during 2-year follow-up.

Outcome measures

The primary outcome was whether a meniscal procedure was performed during the 2-year follow-up period (yes or no). For patients who underwent an ACL reconstruction, arthroscopic findings of the affected knee were systematically described in the surgical report according to the Dutch knee arthroscopy guideline.[15] When patients underwent a meniscal procedure without ACL reconstruction, arthroscopic findings were also reported. When a meniscal procedure was performed, one investigator (SJAvdG) extracted the location and technique of the procedure (meniscectomy or meniscal repair) from the surgical report. During the 2-year follow-up, all additional interventions, arthroscopies and meniscal procedures were registered. We registered whether a meniscal procedure was performed before ACL reconstruction, during ACL reconstruction or after ACL reconstruction.

All included patients underwent an MRI of the affected knee at baseline. MRIs were made on different MRI scanners with a magnetic field strength of 1.5 T or 3.0 T. We used the following MRI pulse sequences: sagittal, axial and coronal proton density turbo spin echo (TSE) sequence (slice thickness 3 mm); sagittal and axial T2-weighted TSE sequence with fat saturation (slice thickness 3 mm). We defined presence of a meniscal tear as a grade 3 meniscal tear. A grade 3 meniscal tear has signal changes on MRI that reach the articular surface of the meniscus and therefore is considered to be a full tear.[8] One investigator (SJAvdG) was trained by a musculoskeletal radiologist with 15 years of experience. This investigator assessed all baseline MRIs and reported whether patients had no meniscal tear, a medial or lateral tear or a tear in both menisci. The investigator consulted an orthopaedic surgeon (DEM) in case the baseline MRI was inconclusive. Together they reached consensus on all MRIs.

Data analysis

The baseline characteristics of the patients were described according to the randomly assigned treatment. The presence and location of meniscal injuries as assessed on baseline MRI were also described for the as randomised treatment groups.

We presented the number of meniscal procedures in a flowchart (figure 1) for the 'as randomised' groups and for each 'as treated' group: patients that underwent early ACL reconstruction, patients who followed rehabilitation therapy during 2-year follow-up (no ACL reconstruction group) and patients that started with rehabilitation therapy and opted for a delayed ACL reconstruction during a follow-up (delayed ACL reconstruction group).

We analysed whether patients had a meniscal procedure in the ACL injured knee during the 2-year follow-up period using a modified Poisson regression, adjusted for sex, body mass index (BMI), orthopaedic surgeon and age group.[16 17] Patients were analysed according to their randomisation group. Dependent variable was meniscal procedure (yes/no), independent variables were randomisation (early ACL reconstruction or rehabilitation plus optional delayed ACL reconstruction), BMI, sex, orthopaedic surgeon and age group (<30 and ≥30 years). In the COMPARE trial, randomisation was stratified for orthopaedic surgeon and age group (<30 and ≥30 years), therefore, we added these factors to the model. We presented the risk ratio (RR) for having a meniscal procedure during follow-up of rehabilitation therapy plus optional delayed ACL reconstruction compared with early ACL reconstruction together with its uncertainty (95% CI).

RESULTS

Patients

Baseline characteristics are reported in table 1. In the early reconstruction group, three patients did not receive an ACL reconstruction, because of tomophobia (fear of surgery) in one patient and a negative pivot shift test during surgery in two patients.

Meniscal injuries on MRI

At baseline 41% (n=69) of the patients in the study population had a meniscal tear. Eighteen per cent (n=30 of 167 patients) had a medial meniscal tear, 12% (n=20 of 167 patients) had a tear in the lateral meniscus and 11% (n=19 of 167 patients) had both a medial and lateral meniscal tear. In the early reconstruction group and rehabilitation plus optional delayed ACL reconstruction group respectively 40% (n=34) and 43% (n=35) of the patients had a meniscal tear on baseline MRI, as shown in table 1.

Meniscal procedures during follow-up

All meniscal procedures are reported in figure 1. In both randomisation groups, 1 patient underwent a meniscal procedure before inclusion, but after the trauma when the ACL ruptured. During

the 2-year follow-up, 25 patients in the early ACL reconstruction group (29%, 25/85 patients) had a meniscal procedure in the ACL injured knee, with 3 patients that had 2 meniscal procedures in the same knee at 2 time points during the follow-up. In the rehabilitation plus optional delayed reconstruction group 17 patients (21%, 17/82 patients) had a meniscal procedure in the ACL injured knee during follow-up, with 3 patients that had 2 meniscal procedures in the same knee at 2 time points during follow-up. The RR for having a meniscal procedure during the follow-up period was 0.67 (95% CI 0.40 to 1.12, p=0.12) for rehabilitation plus optional delayed ACL reconstruction compared with early ACL reconstruction. The model is based on 165 patients, there were two missing values.

In the patients who underwent early ACL reconstruction (n=82), 23 meniscal procedures were performed during reconstruction (28%, 23/82). In the patients who were randomised to rehabilitation therapy but underwent delayed ACL reconstruction during follow-up (n=41), 13 meniscal procedures were performed during reconstruction (32%, 13/41). In the patients that underwent no ACL reconstruction (n=41), 4 meniscal procedures were performed during separate arthroscopies (10%, 4/41) and 1 patient had a second meniscal procedure after the first separate arthroscopy.

After early ACL reconstruction 4 meniscal procedures (5%, 4/82) were performed, compared with 2 procedures (5%, 2/41) after delayed ACL reconstruction. These procedures were performed because of new trauma or knee complaints during follow-up. All six meniscal tears were located in meniscus tissue that was seen to be damaged during initial ACL reconstruction.

DISCUSSION

We found that the number of meniscal procedures in patients with an ACL rupture who were treated with rehabilitation therapy and optional delayed ACL reconstruction does not differ from patients who received early ACL reconstruction. After ACL reconstruction, in both treatment groups no new meniscal procedures were performed in parts of the meniscus other than the area that was already damaged as seen during ACL reconstruction.

We did not find that starting with non-operative treatment with optional delayed ACL reconstruction in patients with an ACL injury increases the risk for additional meniscal procedures in the first 2 years after trauma. This is in contrast to previous findings of studies that compared delayed and early ACL reconstruction.[4 5 18–21] A study of Granan *et al* analysed the Norwegian National Knee Ligament Registry. They concluded that the odds for meniscal tears after an ACL rupture increase with 1% every month that surgery is postponed.[4] Delaying ACL surgery is thought to increase the risk for additional meniscal damage because of an increase in knee instability episodes.[10] In a systematic review Sommerfeldt *et al* found low evidence that recurrent instability after ACL rupture is associated with increased odds for medial meniscal lesions. All studies in this review were classified as 'high risk of bias' and patients undergoing non-operative treatment were under-represented. In a more recent systematic review, Ekås *et al* found insufficient evidence that non-operative treatment increases risk for new meniscal tears.[11] Also in this review the included studies had a high risk of bias. A recent study of Snoeker *et al* (KANON trial) found a two times higher risk for medial meniscal tears in patients that were randomised to rehabilitation therapy treatment plus optional delayed ACL reconstruction after a 5-year follow-up, but not after a 2-year follow-up.[1 12] Despite this higher risk for medial meniscal tears after 5 years, the number of meniscal surgeries during ACL reconstruction and thereafter in both treatment groups of the KANON trial did not differ after 5 years.[22] At 2-year follow-up, the KANON trial reported more meniscal surgeries compared with our study. This can be explained by the fact that in the KANON trial a part of the surgeries was counted per individual meniscus, so a meniscal surgery on both the medial and lateral meniscus was counted twice.

So far, the evidence for the risk of additional meniscal injuries with a delayed ACL reconstruction is inconclusive, mostly because of studies with poor methodology, like observational and register-based studies. However, the two randomised trials in this field with low risk of bias (KANON trial and our study) did not find a difference in the number of meniscal surgeries between early ACL reconstruction and non-operative treatment plus optional delayed ACL reconstruction after 2 years. Further follow-up of our study population will have to show whether the results will change at long term. Longer follow-up may lead to more meniscal surgeries, since with increasing time more traumatic moments can occur, meniscal injuries that are not treated during the study period may become symptomatic at a later time point and increasing age increases the risk for degenerative meniscal tears.

It is plausible that development of additional meniscal injuries after an ACL rupture is also dependent on the patients' activity level. It has been reported that higher activity levels can lead to a more than fourfold increase of the risk for additional knee injuries following ACL rupture.[23] Thus, a different postinjury activity level could also explain the differences between studies investigating secondary meniscal injuries after ACL rupture. Preinjury activity levels in the KANON were higher compared with preinjury activity levels in the COMPARE trial, but activity levels during the follow-up were not reported in neither study.[1 13] A lower postinjury activity level may have influenced the development of meniscal injuries during the follow-up period in two ways. On the one side, a lower activity level may cause less meniscal injuries. On the other side, a lower activity level may also be the consequence of knee complaints because of a meniscal injury. Furthermore, the decision whether a patient needs a delayed ACL reconstruction or not is made by the orthopaedic surgeon and the patient. This introduces selection bias, the risk that the characteristics, like age and activity level, of both groups are not similar. These differences may have influenced the development of additional meniscal injuries. In both our study as well the KANON trial this may have biased the outcome.

All new meniscal tears that occurred after ACL reconstruction in both the early and delayed ACL reconstruction group were located in the same region of the meniscus as the part that was already damaged as seen during the ACL reconstruction. This can be explained either by an insufficient partial meniscectomy or meniscal repair during ACL reconstruction, or because no meniscal procedure was performed during ACL reconstruction. Another reason could be that the torn meniscal horn was already of lower quality because of histological changes.[24] These changes could also have played a role in the initial tearing of the meniscus. We reported in an earlier paper that meniscal tissue of traumatic tears has a higher degree of degeneration compared with healthy meniscal tissue, resulting in a meniscus that is more susceptible to tear.[24] So it could be that this part of the meniscus, although treated during ACL reconstruction, may get injured again more easily than other parts because of the histological changes.

In our study, only 10% (n=4) of the patients in the no ACL reconstruction group received meniscal surgery, although at

baseline 46% (n=19) of the patients had a meniscal tear as seen on MRI. This indicates that during 2-year follow-up only 21% (4/19) of the patients with a diagnosed meniscal tear had symptoms for which a meniscal surgery was performed. The majority of the patients in the no ACL reconstruction group had either no or mild knee complaints. Therefore, neither a knee arthroscopy nor meniscal procedure was performed. As reported earlier by Tornbjerg *et al*, the correlation between a meniscal tear and knee complaints is low, and thus, most patients with a meniscal tear are able to maintain a good knee function.[25] For traumatic meniscal tears, there is no consensus concerning the optimal treatment option, although there is limited evidence that small tears of the lateral meniscus can be left in situ and that other tears should be repaired.[26 27] In our study, most patients in the no ACL reconstruction group did not receive meniscal surgery; however, it is undetermined yet whether these patients will develop meniscal complaints after a longer follow-up period.

The main strength of our study is that this is the second well-performed RCT studying two different treatment strategies for ACL ruptures. In addition, this study is further strengthened by the large study population. Another strength is that we compared meniscal tears between two different treatment strategies for ACL rupture in a randomised controlled setup. This study, therefore, has low risk of bias compared with most previous studies.

A limitation of our study is that we did not perform an additional MRI at 2-year follow-up. Therefore, we reported on meniscal procedures performed during follow-up and could not report all meniscal injuries after 2 years. Patients in the delayed reconstruction group received an ACL reconstruction because of knee symptoms and complaints, which may have influenced the number of meniscal procedures in this group. However, when the treatment groups are compared according to the randomly assigned treatment, the rehabilitation therapy plus optional delayed ACL reconstruction group did not receive more meniscal surgeries than the early ACL reconstruction group. Second, our study is a secondary analysis on a randomised trial and the COMPARE trial was not initially powered to answer the current research question. Third, there may be recruitment bias in the COMPARE trial since 101 of the 282 eligible patients declined to participate in the study because of a strong preference for one of the treatment options (51 preferred surgery and 50 preferred non-operative treatment).[13] Because these preferences were equally divided, the results of our study would likely not have been different if all eligible patients had participated.

In the current study, numbers of meniscal procedures in the early ACL reconstruction and delayed ACL reconstruction group differ from the numbers reported in the previous paper of the COMPARE trial.[13] In the current paper, we reported two additional meniscal procedures which were performed before inclusion in the study. In both the early and delayed ACL reconstruction group, one patient received a meniscal procedure before inclusion. In this paper we also assessed all baseline MRIs, while the previous paper of the COMPARE trial used the MRI reports from the different participating hospitals, resulting in different numbers of meniscal tears on baseline MRI.

In conclusion, in this study, we did not find that initial non-surgical treatment of ACL ruptures followed by optional delayed ACL reconstruction leads to a higher number of meniscal procedures compared with early ACL reconstruction over a 2-year follow-up period.

Contributors MR and DEM conceived and designed the study. All authors acquired, analysed or interpreted the data. SJAvdG and MR performed the statistical analysis. SJAvdG, MR and DEM drafted the manuscript. All authors critically revised the manuscript for important intellectual content. MR and DEM are the guarantors.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Medical Research Ethics Committee of Erasmus Medical Center in Rotterdam, reference number MEC-2010-291. Participants gave informed consent to participate in the study before taking part.

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Data availability statement Data are available on reasonable request. Individual deidentified participant data that underlie the results reported in this paper (text, tables, figures and appendices) and the study protocol will be shared if requested. Data will be available beginning 12 months and ending 5 years after publication of this paper. Data will be available for researchers who provide a methodologically sound scientific proposal, which has been approved by an ethical committee. Proof of the latter should be provided. Analyses should achieve the aims reported in the approved proposal. Proposals for data should be directed to the corresponding author (d.meuffels@erasmusmc.nl).

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