Grip on CPIP

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CHAPTER 8

Uniformity of chronic pain assessment after inguinal hernia repair, a critical review of literature

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Submitted

Abstract

Background

Over the last years various prospective studies have been undertaken to investigate surgery related solutions to minimize the incidence of chronic postoperative inguinal pain (CPIP). The outcome measures and assessment tools used in these studies differ. The purpose of this study is to investigate the quality and uniformity in the assessment of CPIP in prospective studies.

Methods

A systematic literature review identified eighty randomized clinical trials and prospective studies investigating CPIP publised between 2007 until to date. Study designs were checked for the availability of a definition of CPIP, the measurement tools used to quantify and qualify CPIP, the availability of a baseline score and a minimal follow-up of twelve months.

Results

In 61% of the studies formal criteria were given to define CPIP of which half (47%) used the definition given by the International Association for the Study of Pain. In 66% (53/80) of the studies the existence of CPIP was assessed using only validated assessment tools, but a total of 33 different tools were identified. Of al studies 40% had a validated assessment of both pain intensity (PI) and Quality of Life (QOL), 41% and 4% only had a validated assessment of only PI respectively QOL and 15% had no validated assessment at all. The visual analogue scale and Short Form 36 were most commonly used for measuring PI (73%) and QOL (19%). In 15% it was not clear how CPIP was assessed because no information (9%) or non-specified information (6%) was given. A baseline score was performed by 45% of the studies and 75% had a follow-up of at least 12 months.

Conclusion

Prospective studies addressing CPIP and quality of life in case of inguinal hernia treatment have a variable degree of uniformity in type of outcome measures. This hinders proper comparison of study results and firm conclusions about the best treatment or prevention methods for CPIP. We therefore call for a uniform and validated assessment.

Introduction

Chronic postoperative inguinal pain (CPIP) is the most common long-term complication after repair of an inguinal hernia [1]. The reported frequency of CPIP varies widely. In 2000, Poobalan et al reviewed the literature and found an incidence ranging from 0% to 63% [2]. A similar incidence range was reported by Aasvang and Kehlet in an update [3]. The overall incidence of moderate to severe CPIP is considered to be around 10–12% [4]. The consequences of CPIP can be significant for the individual patient in terms of suffering, reduced quality of life (QOL) and sick leave. Since surgical repair of groin hernias is the most commonly performed operation in the western world, the burden of CPIP also has major consequences from the perspective of health care and social support moreover because it is frequently affecting young men [5].

Over the last years numerous prospective studies have been undertaken to investigate surgery related solutions for CPIP. Subsequent reviews have been faced with challenges such as variations according to the population sampled, inconsistencies in the collection of pre-, intra- and postoperative data that may influence the onset of CPIP, lack of formal criteria to define CPIP (time frame, intensity, character) and variations in the assessment tools to quantify and qualify CPIP. Following these differences and inconsistencies in trial designs Kehlet et al had to conclude in 2002 that there is too little information to recommend preventive or therapeutic interventions to reduce CPIP [6]. They called for uniformity and formulated elements which have to be part of the "ideal" study design [6]. However five years later Hanswijck de Jonge et al had to conclude that pain and discomfort scores still vary widely between studies (ranging from 0 to 53%) due to variations in type, quality and accuracy of the instruments used for the evaluation of CPIP [7].

Uniform and validated study designs are needed to enhance the quality and comparability of studies. Therefore, the working group The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) [8] and the International Association for the Study of Pain (IASP) [9] recommended core outcome domains to be considered in the development of studies designed to measure CPIP: (i) pain intensity (PI) (ii) consequences of chronic pain on physical functioning and (iii) emotional functioning, (iv) participants rating of overall improvement. These core outcomes should be measured

prospectively with a follow-up of 1 year using two or more different assessment methods. In addition the authors cited the need for standard definitions and methods for the assessment of pain.

This review aims to analyze if the recommendations of Kehlet, IMMPACT and IASP have lead to more uniformity and quality in the design of studies focussing on CPIP. It is beyond the scope of this review to give a full critical appraisal of the study methodologies.

Methods

Search strategy

The literature search was performed using Medline in Pubmed, Embase and the Cochrane Library. The following mesh terms were combined: 'hernia, inguinal', 'chronic pain', 'herniorraphy', 'Lichtenstein'. MeSH terms were used in conjunction with free text word combinations as this would uncover papers tagged with unsatisfactory MeSH terms and papers not yet fitted with MeSH terms. The search was limited for 'clinical trials', 'English' and 'publication dates: 2007 and forth.

Inclusion criteria

Studies. Prospective studies and study protocols with the Lichtenstein method as the referring technique irrespective of randmisation, sample size, publication status, single or multi centered.

Patients. Adult patients irrespective of gender or type of hernia (primary or recurrent, uni- or bilateral). Although female gender and recurrent hernia are risk factors for CPIP they were not excluded because this review attempts to give a judgment about study methodology and not to give a precise conclusion about the incidence of CPIP.

Interventions. Correction of an inguinal hernia irrespective of the surgical technique

Outcomes. CPIP is among the primary or secondary outcome measures irrespective of the definition used for CPIP and duration of follow up.

The review process was conducted in two steps. First all abstracts were examined according to the eligibility criteria, consulting the full-text papers if in doubt about inclusion. Second, all full-text papers of the selected abstracts were read to finally decide about inclusion.

Methodological quality score

The quality and comparability of the study designs was analyzed by scoring the included studies for:

(1) the availability of a definition of the outcome measure CPIP thereby preferably making use of international criteria
(2) CPIP is analyzed by measuring both PI and the effects of CPIP on daily functioning / QOL thereby making use of validated assessment tools
(3) patient follow up of at least 12 months
(4) availability of a baseline score e.g. preoperative measurement of PI and QOL

One point each was assigned for the availability of one of the above mentioned aspects and each study was assigned an overall methodological quality score ranging from 0 to 4.

The score was based on the main recommendations of the IMMPACT, IASP and Kehlet et al. The neurophysiologic pre- and postoperative assessment mentioned by Kehlet et al was not taken into account. Although this is regarded the most objectively pain measurement it is not yet routine part of clinical trials.

Results

The search produced 234 hits (see PRISMA flowchart in Figure 1). Once limits were applied there remained 109 articles eligible for inclusion. Reading of the full-text articles resulted in another 29 articles being excluded. The main reasons for exclusion at this stage were the study to be in a retrospective setting, a review or comment, no CPIP among the primary or secondary outcomes or reporting longterm follow-up of an already included study. Eighty articles were finally retained. The characteristics of the included studies are shown in Table 1. There were 52 RCT's. The median sample size ranged from 30- to 2499. Most of the articles investigated the Lichtenstein technique regarding different meshes (n=10), fixation methods (Progrip mesh n=13, glue n=10), analgesia (n=3) and way of nerve handling [10] (n=5). Others compared Lichtenstein with pre-peritoneal mesh placement: TEP (n=12), Prolene Hernia System (PHS, n=4),

plug and patch (n=4), Kugel (n=2), TIPP (n=1). Five studies compared Lichtenstein with retroperitoneal mesh placement (TAPP). Seven studies compared the Lichtenstein tension free hernioplasty with non-mesh techniques: Maloney Darn repair, (MDR, n=2), Shouldice (n=1), Desarda (n=1), suture repair (n=2).

CPIP was the main outcome measure in 55 studies. Most of the studies had more than one primary outcome like both acute and chronic pain, recurrence, complications, use of pain medication or QOL.

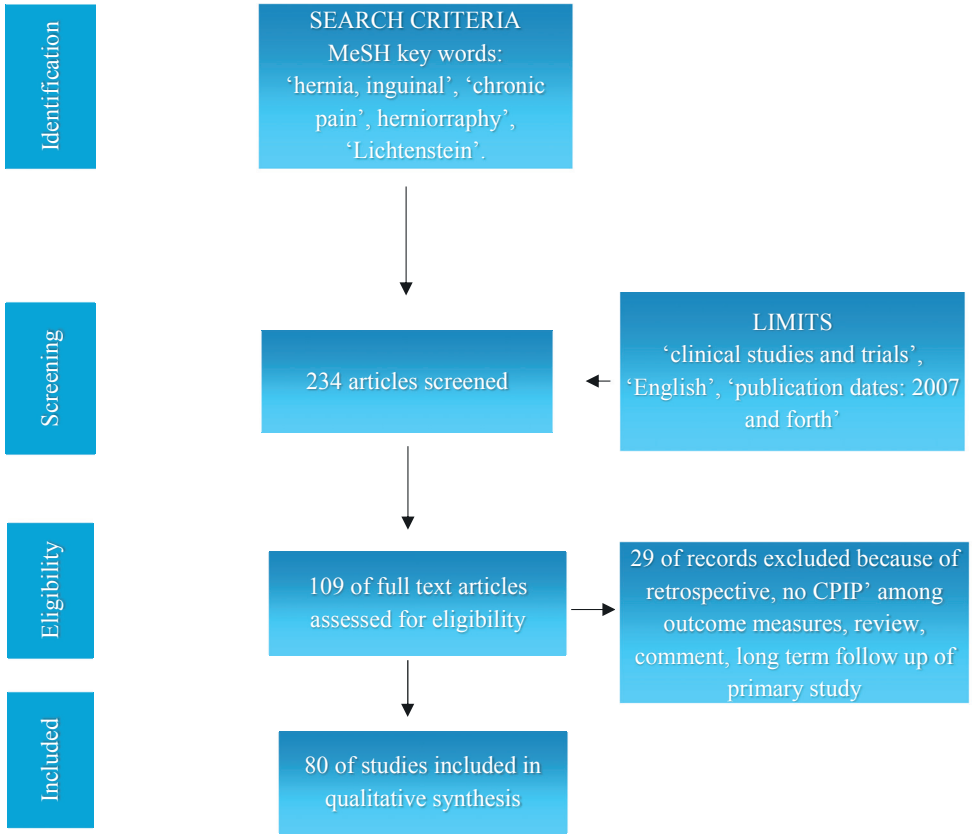

Figure 1. PRISMA flow chart. Overview of the literature search.

1 Definition of CPIP

In 39% (31/80) of the studies no definition or description of CPIP was given (Table 1) [11-41]. In the 61% (n=49) that defined CPIP 22 different definitions of CPIP were practiced (Table 2). Almost half (47% (n=23/49) used the definition of the IASP: chronic pain is pain that persists beyond three months post-operatively [10, 42-64]. The other 53% (26/49) defined CPIP in several ways. First, there was heterogeneity in the post-operative time period after which pain is classified to be chronic pain. Some articles referred to the definition given by Aasvang and Kehlet in which pain is defined to be chronic when lasting 6 months or more [3]. Smietanski et al [65-67] referred to another article of Kehlet et al [6] in which the minimal duration of time was prolonged to 12 months. One study applied 1 month after which pain is defined to be chronic [68]. Second, some authors included pain intensity besides duration in their definition of CPIP. Pain intensity was expressed in several ways: with descriptive terms [69-73], a score on a visual analogue scale (VAS) or a QOL scale like the Carolinas Comfort Scale (CCS) [74]. Some authors used different CPIP definitions in their articles [75, 76].

In addition to providing a definition of CPIP, 31 (39%) studies provided information about how they defined the severity of CPIP (Table 3). Fifteen studies defined the severity of CPIP in the way it affects daily life thereby using 9 different criteria (Table 3). The other 16 studies defined pain severity in terms of pain intensity according to the score on a visual or numerical analog scale (VAS or NAS). The categorisation of pain intensity was highly heterogenic (Figure 2). Some studies defined a minimum VAS score from which CPIP is clinically relevant [17, 77], Others made 2 [78], 3 [11], or 4 [70] categories between zero and ten with the associated incidence rates. Champault et al used different categories in their publications [11, 77]. Furthermore the VAS was both used as a 10, 100 or 150 point scale.

Table 1. Included studies: study characteristics and methodological quality score

First author	Year	Study Design	Research question	N (total)	Measurement tool(s)	PI + QOL assessed with validated tool	Mean length of FU (months)	FU ≥ 12 months	CPIP defined	Basement score
Abd El Maksoud	2014	RCT	L / MDR	227	VAS		12	x		
Anadol	2011	P	L / Progrip mesh	51	VAS, ‘ questionnaire ‘		24	x	x	
Andresen	2013	RCT	L / Onstep approach	282	VAS, AAS, CCS	x	12	x	x	
Beldi	2008	P	L / suture repair / TEP	96	VAS, SF36, von Frey filaments	x	3		x	
Bellows	2011	RCT	L: synthetic / biological mesh	172	AAS, BPI , WBF, PAS	x	24	x	x	
Belyansky	2011	P	L / TEP / TAPP	2499	CCS	x	12	x	x	
Bignell	2014	RCT	L / TAPP	120	SF-12v2, PIQ-6	x	12	x		x
Bochicchio	2014	RCT	L: synthetic / biological mesh	95	SF-36v2, VAS	x	12	x	x	x
Bracale	2014	RCT	L: sutures / glue	102	-		15	x		
Bury	2012	RCT	L with 3 types of mesh	396	VAS, ‘ questionnaire ‘		62	x		
Caliskan	2010	P	nerve management	54	VRS, VAS		6		x	
Campanelli	2012	RCT	L: sutures / glue	319	SF-36v2, VAS	x	12	x	x	x
Champault	2007	P	L / TEP / polypropyleen mesh / Glucamesh	349	VAS, ‘a validated questionnaire’	x	24	x		
Champault	2011	P	Progrip mesh	186	VAS, SF12	x	3			x
Chastan	2009	P	Progrip mesh	52	VAS		12	x		x
Chatzimavroudis	2014	RCT	L / Progrip mesh	50	VAS		12	x	x	
Dalenback	2009	RCT	L / PHS / plug and patch	472	VAS, ‘a standardised scored FAT 2 protocol’	x	36	x		x
Demetrashvili	2011	RCT	L / TAPP	52	VAS		36	x		
Dhankbar	2014	RCT	L / TEP	72	VAS, SF36v2	x	3		x	x
Dhumale	2010	P	L	1164	‘ questionnaire ‘		2		x	
Eker	2012	RCT	L / TEP	660	VAS		60	x		x
Eklund	2010	RCT	L / TEP	1370	IPQ, VAS, FIS	x	60	x	x	x
Eklund	2007	RCT	L / TAPP	1512	VAS, ‘ a validated questionnaire ‘, FIS	x	60	x	x	x
El-Awady	2009	P	L	40	SF36		9		x	x
Ferranti	2009	P	Self regulating prothesis	214	-		24	x		
Fortelny	2014	RCT	L: sutures / glue	38	VAS, SF36	x	12	x		x
Fricano	2010	P	Modificated L	406	PIC, VRM, ‘ questionnaire ‘		6		x	
Frisen	2011	P	L: resident / surgeon	200	SS, IPQ	x	3			x
Garcia Urena	2011	P	Progrip mesh	256	VAS, ‘ questionnaire ‘		6		x	
Holzheimer	2007	P	L	300			12	x		
Honigmann	2007	RCT	L: Local anaesthesia	264	VAS, PMD, SF36.	x	12	x	x	x

First author	Year	Study Design	Research question	N (total)	Measurement tool(s)	PI + QOL assessed with validated tool	Mean length of FU (months)	FU ≥ 12 months	CPIP defined	Basement score
Jain	2009	P	L: sutures/glue	80	- (VAS was used for acute pain)		12	x	x	
Jeroukhimov	2014	RCT	L: non-absorbable / absorbable sutures	200	VRS		12	x	x	
Jorgensen	2012	RCT	L / Progrip mesh	334	VAS		12	x	x	x
Kapischke	2010	RCT	L / Progrip mesh	50	VAS, ' telephone interview'		6		x	
Karakayali	2010	RCT	nerve management	240	VAS, SF6, MPQ	x	12	x		
Karakayali	2007	P	L / Shouldice	100	VAS, EMG, ' questions about daily complaints '		12	x		
Kim-Fuchs	2012	RCT	L: sutures / glue	264	' a questionnaire '		60	x	x	
Kingsnorth	2012	RCT	L / Progrip mesh	302	VAS 0-150mm, SPS		12	x		x
Koch	2008	RCT	L: HW mesh / LW mesh	317	VAS, SHS	x	2			x
Koning	2012	RCT	L / TIPP	302	VAS, SF36, PPT	x	12	x	x	
Kouhia	2009	RCT	L / TEP	99	-		24	x		x
Kucuk	2010	RCT	L / MDR	306	-		6		x	
Kurmann	2014	RCT	L: Local anaesthesia	357	VAS		12	x	x	x
Langeveld	2010	RCT	L / TEP	660	0-6 weeks: VAS, SF36, after six weeks: interview	x	60	x		
Lauscher	2008	P	L / TEP	491	NAS, ' a validated questionnaire '	x	58.6	x		
Lionetti	2012	RCT	L: sutures / glue	148	VAS, ' a questionnaire '		12	x		
Magnusson	2012	RCT	L / PHS / UHS	309	VAS, SF36, ' a questionnaire '	x	12	x		x
Malekpour	2008	RCT	L: nerve management	121	VAS, ' a questionnaire '		12	x	x	
Myers	2010	P	L / TEP	314	SF36		60	x	x	
Negro	2011	P	L: sutures / glue	520	VAS		12	x		x
Nienhuijs	2007	RCT	L / Kugel	172	VAS, ' a pain questionnaire '		3		x	x
Nienhuijs	2014	RCT	L / PHS / MPR	270	VDS, VAS	x	86	x	x	
Nikkolo	2010	RCT	L: HW mesh / LW mesh	35	VAS, SF36	x	12	x	x	x
Nikkolo	2014	RCT	L : different pore size meshes	134	VAS, SF36	x	6		x	
Paajanen	2011	RCT	L: absorbable sutures / glue	59	VAS		12	x	x	x
Paajanen	2013	RCT	L: 3 types of mesh	228	VAS, interview based on the DHD		56	x	x	x
Pedano	2012	P	Progrip mesh	181	-		17	x	x	
Pielacinski	2011	RCT	L / absorbable mesh	358	VAS, VRS		6			
Pierides	2012	RCT	L / Progrip mesh	358	VAS, ' a questionnaire '		12	x		x
Pierides	2011	RCT	L / PHS	232	' a questionnaire '		60	x		
Quyn	2012	P	L / Progrip mesh	132	SF36		12	x	x	

First author	Year	Study Design	Research question	N (total)	Measurement tool(s)	PI + QOL assessed with validated tool	Mean length of FU (months)	FU ≥ 12 months	CPIP defined	Basement score
Reinpold	2011	P	nerve management	781	VAS, interview, 'a standardised questionnaire'		60	x	x	x
Ripetti	2014	RCT	L / Trabucco / Valenti	162	-		96	x	x	
Ruiz-Jasbon	2014	P	L	40	VAS, IPQ	x	36	x	x	x
Sadowski	2011	RCT	L: polypropylene / polyester	78	VAS, IPQ, 'a questionnaire '	x	3		x	x
Sanders	2009	RCT	L / Perfix Plug / ProLoop plug	295	VAS		12	x	x	
Sanders	2014	RCT	L / Progrip mesh	557	VAS, SPS	x	12	x		x
Shen	2012	RCT	L: sutures / glue	110	VAS		12	x	x	x
Singh	2011	RCT	L / TAPP / TEP	117	SF36, SPS	x	12	x	x	x
Smeds	2010	P	nerve management	525	VAS		3			x
Smietanski	2009	P	L with monofilament mesh	212	VAS		36	x	x	
Smietanski	2008	RCT	L: HW mesh / LW mesh	392	SF36, VAS	x	12	x	x	x
Smietanski	2011	RCT	L: HW mesh / LW mesh	202	SF36, VAS	x	60	x	x	
Staal	2008	P	L / Kugel	172	VAS, PDI	x	3		x	x
Szopinski	2012	RCT	L / Desarda	216	VAS, ShS	x	36	x	x	
Veen	2007	RCT	L / suture repair	153	' a questionnaire '		129	x	x	
Wong	2011	RCT	L: glue / sutures	56	VAS		6			
Yalcin	2009	P	L: local anesthesia	115	VAS		12	x		
Yilmaz	2013	P	L / Progrip mesh	60	VAS		4		x	x

FU = Follow-up; RCT = Randomized Controled Trial; P = Prospective; / = versus; L = Lichtenstein; MDR = Modified Darn Repair; TEP = Total Extra Peritoneal Repair; TAPP = Trans Abdominal Pre Peritoneal Repair; PHS = Prolene Hernia System; UHS = UltraPro Hernia System; MPR = Mesh plug Repair; HW = Heavy weight; LW = Light weight; TIPP = Trans Inguinal Pre Peritoneal repair; VAS = Visual Analog Scale; AAS = Activities Assessment Scale; CCS = Carolinas Comfort Scale; SF36 = Short Form Health Survey 36; BPI = Brief Pain Inventory; WBF = Wong Baker Faces rating scale; PAS = Pain Assessment Survey; SF-12v2 = Short Form Health Survey 12 version 2; PIQ = Pain Impact Questionnaire (QualityMetric, USA); VRS = Verbal Rating Scale; IPQ = Inguinal Pain Questionnaire; PIC = Pain Intensity Scale; VRM = Verbal rating Model; SS = Sergel Score; PMD = Pain Matcher device (Cefar Medical AB, Lund, Sweden); MPQ = Mc Gill Pain Questionnaire; EMG = Electromyelogram; SPS = Surgical Pain Scale; SHS = Short Health Scale; NAS = Numeric Analog Scale; VDS = Verbal Descriptor Scale; PDI = Pain Disability Index; ShS = Sheffield Scale

The methodological quality and comparability of the literature on CPIP was analyzed by scoring the included studies for:
(1) CPIP is defined thereby making use of standard internationally practiced criteria
(2) both PI and effects of CPIP on QOL are measured thereby making use of validated assessment tools
(3) sufficient follow up of at least 6 months
(4) availability of a baseline score e.g. preoperative measurement of PI and QOL
One point each was assigned for the availability of one the above mentioned aspects and each study was assigned an overall methodological quality score ranging from 0 to 4.

Table 2. Overview of the different definitions of Chronic Post-operative Inguinal Pain (CPIP) used in the included studies

First author	Definition of CPIP
n=49 (61%)	
Anadol, Beldi, Bellows, Chatzimavroudis, Dhankhar, Eklund (2x), El-Awadj, Fricano, Honingman, Jeroukhimov, Kapinschke, Kim Fuchs, Koning, Malekpour, Myers, Nienhuijs 2x, Quijn, Sanders 2009, Sadowski, Singh, Staal (n=23)	IASP: any VAS lasting >3 months
Andresen	Pain-related impairment of function at 6 months defined as AAS > 8.3 Pain that impairs daily function at the 12-month
Jain, Ripetti	Proportion of patients with pain that impairs daily function at 12 months
Smietanski 3x	Pain lasting >12 months (Kehlet)
Caliskan	Pain lasting >1 months
Ruiz-Jasbon	Pain at 36 months
Pedano	Invalidate pain > 3 months
Yilmaz	VAS >0 at 4 months
Campanelli, Jorgensen	VAS >30 at 12 months
Kurmann	VAS as ≥30 in any quality (at rest, lying, walking, climbing stairs, and bending over) at 3 months
Garcia Urena	VAS >3 at 3 and 6 months
Bochicchio	Any VAS at 3 and 12 months
Kingsnorths	VAS 45/150 lasting >3 months
Shen	moderate or greater pain (VAS > 4) in the inguinal area at 3 months
Belyansky	CCS >1 lasting >3 months
Kucuk	Pain lasting >2 months and requiring painkillers
Nikkolo 2x	Pain at rest at 6 months
Paajanen 2011	VAS >2 lasting >3 months
Paajanen 2012	VAS > 3 at 12 months
Reinpold	Pain once a fortnight lasting >6 months
Szopinski	Moderate or strong pain lasting >6 months
Veen	Pain interfering with daily activities

IASP = International Association for the Study of Pain; VAS = Visual Analogue Scale; AAS = Activities Assessment Scale; CCS = Carolina Comfort Scale; > = more than

Table 3. Overview of the different definitions and categories of pain severity

First Author	Categories of CPIP
Anadol	"intolerable pain" = "intractable" or "hard to live with" and those pain which requires pain medication and/or medical consultation
Szopinski	**Sheffield scale:** 0 = no pain 1 = no pain at rest but it appears during movement 2 = temporary pain at rest and moderate during movement 3 = constant pain at rest and severe during movements
Eklund (2x), Smietanski	mild = occasional discomfort or pain not interfering with daily activities moderate = discomfort or pain occasionally interfering with daily activities severe = discomfort or pain interfering with daily activities
Veen	pain and discomfort whether or not interfering with daily activity
Lionetti	**Cunningham's criteria:** Mild = occasional pain or discomfort that did not limit activity, with a return to pre-hernia lifestyle Moderate = pain preventing return to normal preoperative activities (inability to continue any sports or to lift objects without pain) Severe = pain constantly or intermittently present but so severe as to impair normal activities, such as walking.
Jeroukhimov	Mild = occasional pain or discomfort that did not limit daily activity and did not require pain medicine. Moderate = pain that interfered with a return to normal everyday activity with rare analgesic requirement. Severe = pain that incapacitated the patient, occurred at frequent intervals, or interfered with everyday activities with a frequent need for painkillers.
Nienhuijs	Pain was graded into non/mild/moderate and severe using a **Verbal Discriptor Scale** (VDS) for different aspects of life
Kingsnorth, Sanders, Singh	**Surgical Pain Scale**: measures pain while at rest, during normal activities, during work or exercise, and pain unpleasantness.
Belyansky	relevant pain = CCS>1
Ruiz-Jasbon, Sadowski	pain yes or no in different situations according to **Inguinal Pain Index**: if yes a score on a VAS was asked
Andresen	moderate to severe pain = VAS 4-10
Campenelli	relevant pain = VAS>30
Dalenbäck	severe = VAS >70
Champault, Demetrashvili	mild = VAS <30, moderate = VAS <50, severe or debilitating = VAS >50
Champault, Jorgensen	mild = VAS 1–30, moderate = VAS 31–60, severe = VAS>60
Nikkolo 2x	mild = VAS 1-10, moderate = VAS 11-50, severe = VAS >50
Reinpold	not relevant CP: mild CP = VAS 1-3, relevant CP: moderate CP= VAS 4–6, strong CP= VAS 7–9, very strong CP =VAS 10
Karakayali (2x), Koning	mild = VAS 1-30, moderate = VAS 40-70, severe = VAS>70
Szopinski	moderate = VAS 30-54, strong = VAS>54
Kapischke	low to medium = VAS 0-40; medium to strong = VAS >40
Lauscher	weak = NAS 1-3, moderate/severe = NAS>3

VAS - Visual Analog Scale, in the studies ranging from 0=10 or 0=100; NAS = Numeric Analog Scale; CCS = Carolinas Comfort Scale; CP= chronic pain

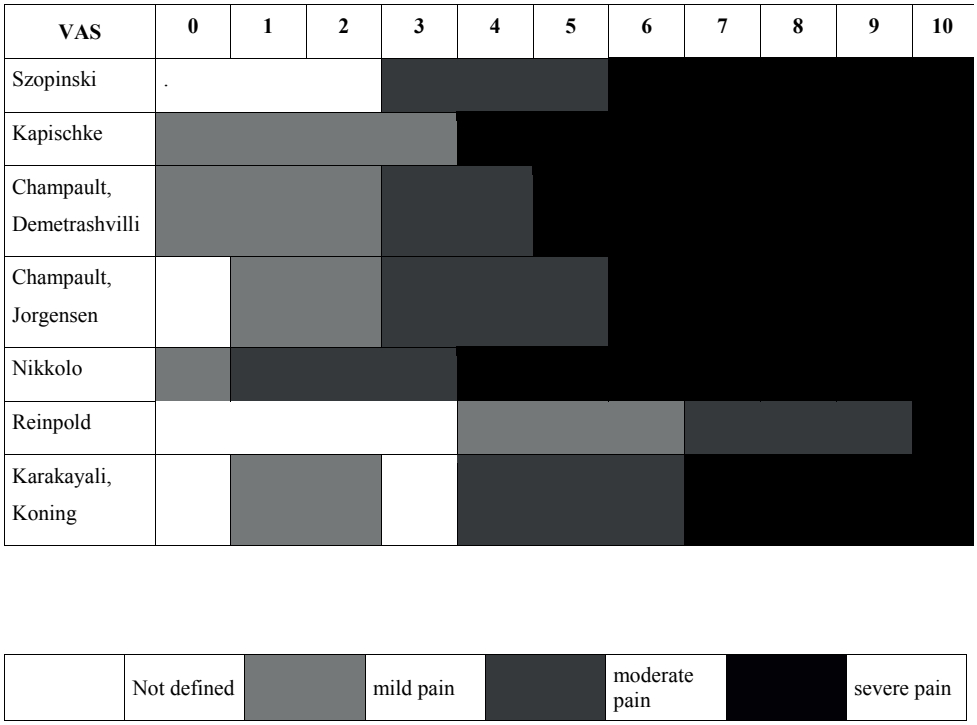

Figure 2. Categories of CPIP based on VAS score. Thirty-one (39%) studies provided information about how they defined the severity of CPIP (Table 3). Most of these studies (n=15) defined pain severity in terms of pain intensity according to the score on a Visual analog scale (VAS) or numerical analog scale (NAS). The categories of pain intensity based on VAS scores were highly heterogenic and thus not comparable.

2.1 Use of a validated assessment tool(s) for the evaluation of CPIP.

In *66%* (53/80) of the studies only validated assessment tools were used, but a total of 33 different tools was identified (Table 4, 5, 6) [10, 14, 16, 17, 20, 22, 24-29, 31, 32, 34, 35, 39, 41, 44, 46, 48-50, 53, 55, 58-68, 72-75, 77-88]. In three studies it was not clear which validated tool was used [11, 43, 78].

In 24% (19/80) of the studies non-validated questionnaires or separated questions (written or by interview) were used [13, 21, 23, 30, 33, 36-38, 43, 45, 47, 51, 52, 54, 56, 57, 70, 76, 89, 90]. In these studies it was mentioned 'a questionnaire was used' or 'patients were interviewed about…'. In 4 (5%) studies this was the only measurement tool used [21, 23, 30, 57, 89]. Fifteen (19%) had a validated assessment tool in conjunction: VAS [13, 33, 36-38, 43, 45, 47, 52, 54, 70, 76, 90], VRM [51], Inguinal Pain Questionnaire (IPQ) [56], or Functional Index Score (FIS) [43].

Table 4. The number of studies that uses validated or non-validated assessment tools to measure CPIP

Type of assessment tool used	Number of studies (%)
No information given	8 (10%)
Non validated questionnaire: separated questions, written or by interview	19 (24%)
- As a single measurement tool	4
- In combination with a validated pain intensity score	12
- In combination with a validated pain intensity and QOL score	3
Only validated questionnaire(s) or pain intensityscale (number of different tools n = 30)	53 (66%)

QOL = quality of life;

Table 5. Tools used to measure CPIP

Shortening	**Full name**	**Number of studies it is used in**
AAS	Activities Assessment Scale	3
BPI	Brief Pain Inventory	1
CCS	Carolinas Comfort Score	2
DHD	Danish Hernia Database questionnaire	1
FAT	Functional Ability test	1
FIS	Functional Index Score	2
IPQ	Inguinal Pain Questionnaire	4
MPQ	Mc Gill Pain Questionnaire	1
NAS	Numeric Analog Scale	1
PAS	Pain Assessment Survey	1
PDI	Pain Disability Index	1
PIQ-6	Pain Impact Questionnaire	
PIC	Pain Intensity Scale	1
PPT	Pin Prick Test	1
PMD	Pain Matcher Device	2
SF12 / SF12v2	Short Form 12 / Short Form 12 version 2	2
SF36 / SF36v2	Short Form 36 / Short Form 36 version 2	16
SF-6D	Short Form – 6 Dimensions	1
SHS	Short Health Scale	2
SPS	Surgical Pain Scales	3
ShS	Sheffield Scale	1
SS	Sergel Score	1
VAS-100mm	Visual Analog Scale 0-100mm	57
VAS-150mm	Visual Analog Score 0-150mm	1
VDS	Verbal Discriptor Scale	1
VRM	Verbal Rating Model	1
VRS	Verbal Rating Scale (0-100)	3
VRS-4	Verbal Rating Scale (0-4)	1
WBF	Wong-Baker Faces Rating Scale	1
FF	von Frey Filaments	1
	a validated questionnaire ‘	3

In 10% (8/80) of the studies there was no information provided about data collection [12, 18, 19, 40, 69, 71, 91]. In 3 studies neurophysiologic tests were used: Fon Frey Filaments [46], EMG [13], pin prick test [58].

Table 6. Tools used to assess QOL and or pain intensity

Quality of Life (QOL) or Functional assessment	Pain Intensity (PI)	QOL + PI
Activities Assessment Scale	Numeric Analog Scale	Carolinas Comfort Score
Activity Restriction Questionnaire	Pain Intensity Scale	Brief Pain Inventory
Danish Hernia Database questionnaire	Pain Matcher Device	Mc Gill Pain Questionnaire
Functional Ability Test	Pin Prick Test	Short Health Scale
Functional Index Score	Surgical Pain Scale	Inguinal Pain Questionnaire
Pain Disability Index	Sheffield Scale	
Short Form 12 / 12-2v	Sergel Score	
Short Form 36	Visual Analog Scale 0-100mm	
Short Form – 6 Dimensions	Visual Analog Score 0-150mm	
Pain Impact Questionnaire	Verbal Rating Model	
	Verbal Rating Scale	
	Verbal Discriptor Scale	
	Wong-Baker Faces Rating Scale	

2.2 *Validated assessment of both pain intensity and QOL / daily functioning*

In 40% (32/80) (Tables 1) of the studies there was a validated assessment of both PI and QOL [14, 17, 22, 23, 25, 27, 32, 37, 41, 43, 44, 46, 48, 50, 55, 56, 58, 60, 62, 64, 65, 67, 72-74, 77, 78, 80, 84-87]. In 41% (33/80) there was only a validated assessment of PI [10, 11, 13, 16, 20, 24, 26, 28, 29, 31, 33-36, 38, 39, 45, 47, 51, 52, 54, 61, 63, 66, 70, 75, 76, 79, 81-83, 88, 90], in 4% (3/80) only QOL was assessed with a validated tool [49, 53, 59]. In 15% (12/80) of the studies no validated assessment tool was utilized to measure PI or QOL [12, 18, 19, 21, 30, 40, 57, 69, 71, 89, 91].

The assessment of PI en QOL was mostly by VAS and SF36 respectively. (Table I and VI). Among the tools that incorporate the assessment of both PI and QOL the Inguinal Pain Questionnaire was used most. Some used rating scales like the Verbal DescriptorScale to measure QOL [31].

4 Availability of a baseline score: preoperative measurement of PI and its consequences for daily functioning / QOL

A baseline score was performed by 45% (36/80) of the included studies (Table I).

5 Sufficient long term follow-up of at least 12 months

The duration of follow-up ranged from 6 weeks to 96 months. 75% (60/80) had a follow-up of 12 months or longer (Table VII).

Methodological quality score

The full amount of 4 points was scored by 11% of the studies, 26% scored 3 points, 38% scored 2 points, 23% scored 1 point and 2% scored 0 points (Table 7). When comparing the periods 2007-2010 and 2011 until to date there is a significant improvement of the Methodological quality score (P=0.005).

Table 7. Methodological Quality Score

	overall		2007-2010		2011-2015		
	N	%	N	%	N	%	
	80		33		47		
4 points	9	11%	5	15%	4	9%	
		100%		56%		44%	
3 points	21	26%	2	6%	19	40%	
		100%		10%		90%	
2 points	30	38%	15	45%	15	32%	
		100%		50%		50%	
1 point	18	23%	11	34%	7	15%	
		100%		61%		39%	
0 points	2	2%	0	0%	2	4%	
		100%		0%		100%	
							P=0.005 by chi squared test

The methodological quality and comparability of the literature on CPIP was analyzed by scoring the included studies for:
(1) CPIP is defined thereby making use of standard internationally practiced criteria
(2) both PI and effects of CPIP on QOL are measured thereby making use of validated assessment tools
(3) sufficient follow up of at least 6 months
(4) availability of a baseline score e.g. preoperative measurement of PI and QOL
One point each was assigned for the availability of one the above mentioned aspects and each study was assigned an overall methodological quality score ranging from 0 to 4.

Discussion

In 2002 respectively 2005 and 2007 Kehlet et al [6], IMMPACT [8] and IASP [9] formulated standard definitions, core outcome domains and validated methods for studies investigating chronic postoperative pain. The purpose of these formulations was

to enhance the methodological quality and uniformity. Without uniformity in study designs it is difficult to compare study results and to draw conclusions about the best treatment or prevention method for chronic pain. This review aimed to find out whether these formulations are put into practice by studies on CPIP published since 2007:

> A small majority of studies provided a definition of CPIP. In 66% of studies a validated assessment tool was used to measure CPIP, though 33 different tools were used. With respect to the measurement of PI and QOL in a minority of cases (40%) a validated assessment tool was used and in a majority of cases (55%) there was no preoperative baseline measurement. In 75% of studies follow-up was at least 12 months. Therefore, it can be concluded that the advices formulated by Kehlet et al, IASP and IMMPACT have not lead to uniformity and high quality of the design of trials addressing CPIP.

The design of a trial starts with the definition of the outcome measures. In this review only 61% of the articles gave formal criteria of the outcome measure CPIP (Table II) of which almost half (47%) used the IASP definition of chronic pain: chronic pain is any pain that persists beyond the normal tissue healing time usually taken to be 3 months [42]. The other half used 21 different CPIP definitions. Apparently opinions differ after which time period acute pain stops and chronic pain begins. This is not surprising when realizing that also the IASP uses different definitions for chronic pain and persistent post surgical pain (PPSP): pain that develops after a surgical intervention and lasts at least two months excluding other causes for the pain [9]. Aasvang and Kehlet argued that given the possibility of an ongoing inflammatory reaction to a prosthetic mesh, CPIP should be measured at least three to six months postoperatively to provide useful information [3]. Others used a minimum duration of twelve months based on another article of Kehlet et al [6]. Among international expert consensus CPIP is defined as chronic inguinal post operative pain that still exists and affects daily life six months of post-operatively [92].

The definition of CPIP provided by the IASP is based solely on a time factor as it regards discomfort to be pain scoring any VAS above zero. Others incorporated a pain intensity factor in their CPIP definition stating for example that a minimum VAS score of 2 or 3 on a scale of 10 is required to be able to speak of pain. Others added descriptive term

of pain severity in their CPIP definition (Table II) such as discomfort or pain happening once a fortnight, requiring painkillers or interfering with daily activities. These different thresholds of the severity and duration from which one can speak of chronic pain influences prevalence rates and hinders comparisons between studies.

Ideally outcome measurement tools should be validated. Furthermore if a worldwide standard measure of a particular health outcome exists, any study not using it should indicate why it chooses another measure and how their measure is related to the more common accepted measure enabling comparison of study outcomes [93]. This raises the question of which tool is best to be used in the assessment of CPIP. Several pain assessment tools are available that measure different aspects of pain. Pain intensity is mostly measured using verbal rating scales (VRS), numerical rating scales (NRS) and visual analog scales (VAS) [94]. In this review the VAS was predominantly used (73%). These PI scales however just permit a global estimation of a patient's pain not considering all the aspects and consequences of chronic pain (CP). Chronic pain has a major impact on physical, emotional, and cognitive function, on social life and on the ability to work and secure an income [2]. The importance to explore the repercussions of CP as perceived by the patient was demonstrated by Fredheim et al. [95]. They found that patients with non-cancer related CP reported even worse QOL than dying cancer patients. Therefore Kehlet et al and IMMPACT emphasized that a meaningful assessment of CP requires both quantitative measurement tools and multidimensional qualitative tools like health-related QOL instruments [6]. The Medical Outcome Survey Short-Form-36 (MOS SF-36 or SF36) is frequently referred to as the gold standard in QOL measurement. The advantage of the generic SF36 is that it is well known by regulatory bodies and doctors and changes in QOL can be benchmarked against other diseases and treatments. However some argue that the impact of CPIP on QOL is better assessed by a disease-specific QOL measure [96]. In this review four hernia-specific QOL measures were identified and used in eight studies: the Carolina Comfort Scale (CCS) [73, 74], the Inguinal Pain Questionnaire (IPQ [27, 50, 56, 86], Activities Assessment Scale (AAS) [55, 73] and a questionnaire based on the Danish Hernia Database (DHD) [97]. Sometimes rating scales like the VDS were used to measure QOL [64]. There are also questionnaires that incorporate assessment of PI (sensory dimension) and the degree of interference of CP with aspects of daily life (reactive dimension). Examples are the general McGill Pain Questionnaire, Short-Health Scale, Brief Pain Inventory

(BPI) [98] and the hernia specific CCS and IPQ. Besides this, objective methods like pain evoked responses and quantitative sensory testing are gaining popularity but are not regular used yet. Deciding which questionnaire to use is difficult when there is no real consensus about it.

In more than half of studies a baseline measurement of PI and QOL was lacking. This baseline measurement is needed for a meaningful interpretation of postoperative results. Furthermore preoperative pain is a known risk factor for developing CPIP and therefore has to be explored [99].

A study methodology incorporating well defined standard outcome parameters evaluated with validated tools and sufficient follow-up is essential for clinical trials. This was also stressed by the National Institute for Health and Clinical Excellence (NICE) in 2005. In this review 40% had a validated assessment of both PI and QOL, 61% provided a definition of the outcome parameter CPIP and 75% had sufficient follow-up. However 15% had no validated assessment at all, thirty-three different validated questionnaires were used and 22 different CPIP definitions practiced. It can be argued that it takes some time for the recommendations provided by Kehlet et al, IMMPACT and IASP to take into effect. Indeed the methodological quality score is significantly higher (P=0.005) for the period 2011 and onwards compared to the period between 2007 and 2011. Nevertheless there is a need to improve the quality and uniformity of study methodologies further.

In conclusion, heterogeneity with respect to the definition of CPIP including the duration, intensity and severity is high between prospective studies investigating CPIP after inguinal hernia repair published from 2007 up to now. The same applies to QOL, duration of follow up, type of measurement tools used and way of formulating outcomes. Therefore, we propagate to define chronic pain as persistent or recurrent pain lasting longer than 3 months, as suggested by the IASP. Studies investigating CPIP should record the pre-operative baseline pain level and QOL. Furthermore, they should record postoperative pain levels and QOL with a follow-up of at least 12 months. Validated measurement tools should be utilized to quantify and qualify CP and QOL. Whether certain types of measurement tools should be recommended to improve even more the uniformity among studies is open for discussion and could be discussed by for example

the working group that is currently designing a global guideline on treatment of inguinal hernia or by an expert panel in a consensus based model. In our opinion an easy to use hernia specific score incorporating assessment of both PI and QOL would be preferable.

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