Quality of Life assessment using SF-36 and Carolinas Comfort Scale questionnares in patients of Inguinal Hernia undergoing Open Mesh Hernioplasty.

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ABSTRACT

Introduction - Standard treatment of Inguinal hernia is Mesh Hernioplasty. Inguinodynia and foreign body sensation of mesh are major concerns affecting life activities. Western literature revealed Carolinas Comfort Scale (CCS) to be more relevant in assessing Quality of Life (QOL) in hernia cases in comparison to commonly used SF-36. Studies on QOL after hernia surgery in Indian population are scarce. Therefore, a prospective observational study was conducted.

Method - QOL was assessed using SF-36 and CCS in 100 cases of uncomplicated Inguinal Hernia undergoing Open Mesh Hernioplasty. QOL was measured pre-operatively, at one month and six months post-operatively. Finally, they were asked to rate the questionnaire in terms of ease of understanding, liking, better suitability and preference of questionnare in relation to mesh. Statistical analysis was done using SPSS Version 21.0. The values were represented in Number (%) and Mean \pm SD.

Results - Majority of patients found CCS to be more likeable, as compared to SF-36 (94.0%), easy to understand (98.0%), preference to fill if given a choice (94.0%) and more reflective of problems of mesh (100.0%). For assessment of concurrent validity between CCS and SF-36, two scales were correlated and an inverse and mild correlation was observed between the two.

Conclusion -Above findings indicate that CCS can be used to assess the Quality of Life of Inguinal Hernia patients, as it is more patient friendly and capable of dealing with specific problems of Mesh.

Key Words: Inguinal Hernia, Mesh Hernioplasty, Quality of Life, SF-36, Carolinas Comfort Scale

INTRODUCTION

Inguinal hernia is the most common abdominal wall hernia and therefore, Inguinal hernia repair is also one of the most often performed surgical procedures. Worldwide, approximately 20 million Inguinal hernia repairs are accomplished each year [1], since preferred mode of treatment issurgery. Among different surgical modalities are herniotomy, herniorrhaphyand hernioplasty [2].

Some of the common methods of choice for inguinal hernia repair include[3]: 1. Lytle's repair 2. Bassini's repair 3. Shouldice's repair 4. Darn repair 5. Lichtenstein repair (Mesh repair) 6. Stoppa's repair 7. External obliqueaponeurosis (Desarda) repair 8. Laparoscopic hernioplasty.

Tension free mesh repair has become standardmethod of treatment for inguinal hernia[4]. It can solve any anatomical problem in recurrent inguinal hernia[5,6]. Mesh can create new clinical problems e.g. foreign body sensation in the groin, discomfort and abdominal wall stiffnessand Surgical-site infections which may affect the everyday functioning of the patient[7,8,9].

Traditionally, QoL was measured by assessing post-operative pain and or achieving pre-operative functions. This was done by measuring pain using specialized tools like Visual Analog Scale (VAS), Verbal Descriptor Scale (VDS), Verbal Numerical Rating Scale (VNRS) etc., while the functional outcomes were measured using surgery specific tools like GLQI for Gastro-intestinal surgery, ROM for Orthopaedic surgeries etc. However, towards the end of the 20th century, a naive tool was conceptualized and named as Short Form-36 (SF-36)[10,11] to assess 8 important health concepts: 1) limitations in physical activities because of health problems; 2) limitations in social activities because of physical or emotional problems; 3) limitations in usual role activities because of physical health problems; 4) bodily pain; 5) general mental health (psychological distress and well-being); 6) limitations in usual role activities because of emotional problems; 7) vitality (energy and fatigue); and 8) general health perceptions.

However, a need for QoL assessment post-hernia repair was felt, given its high incidence and prevalence. This led to the invention of a new tool called the Carolinas Comfort Scale (CCS). CCS is a Likert scale and also measures the sensation of mesh in different positions and functions. Nonetheless, there seems to be a gap in literature, especially in India, measuring QoL using CCS.

In view of this lack in QOL assessment of patients undergoing hernioplasty, the researchers are now focusing on evaluating the QOL in patients post-hernioplasty. Unfortunately, contemporary literature is also scarcefor QOL assessment in open Mesh hernioplasty.

Hence, the present study was carried out to assess Quality of Life of patients undergoing Open Mesh Hernioplasty in a tertiary care centre at Sitapur.

AIM & OBJECTIVES

AIM-

Comparison of CCS with SF-36 for Quality-of-Life assessment of patients undergoing Inguinal Open Mesh Hernioplasty at HIMS, Sitapur.

OBJECTIVES-

Primary-: To Estimate CCS and SF-36 in patients undergoing InguinalOpen Mesh Hernioplasty.

Secondary: To demonstrate any changes over time in health related QOL using CCS and SF-36.

PATIENTS AND METHODS

A Prospective Observational study was conducted for a period of 18 months at the Department of General Surgery, Hind Institute of Medical Sciences, Sitapur, Uttar Pradesh on patients undergoing Inguinal open mesh hernioplasty. 100 consecutive patients of more than 18 years of age, admitted for Inguinal open mesh hernioplasty, who gave consent were included (Inclusion criteria). Patients having Complicated hernia- with obstruction and strangulation, Hernia with hydrocele or scrotal abscess and patients willing for Laproscopic inguinal hernia repair were excluded (Exclusion Criteria).

Patients' demography and operative details were collected by directinterview or telephonically and proforma forms were filled by doctors, who were not part of operating team to reduce bias. All the patients were administered Carolinas Comfort Scale (CCS) and Short Form (SF-36) questionnaire pre and post-operatively follow-up at 1 month and 6 months.

The SF-36 measures the following eight domains of quality of life: physical functioning (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role-emotional (RE) and mental health (MH). Scores for these domains range from 0 to100, with 100 being the optimal level of function.

The CCS is a 23-item, Likert-type questionnaire that measures severity of pain, sensation and limitation of movements due to mesh in the following eight categories: laying down (LD), bending over (BO), sitting up (SU), activities of daily living (ADL), coughing or deep breathing (CB), walking (W), climbing stairs (S) and exercise (E). The CCS score is derived by adding the scores from each of the 23 items. The best possible score is 0 and the worst possible score is 115.

Questionnaire were used after translating it in vernacular language, the parameters of questionnaire were tabulated and the respondents were asked to rate the questionnaire in terms of ease of understanding at the end, patients were asked the following four questions: 1. Which questionnaire do you like better? 2. Which questionnaire is easier to understand? 3. Which questionnaire is more reflective of the problems you have with your mesh? 4. Given the choice, which questionnaire would you rather fill out?

Statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 21.0 statistical Analysis Software. The values were represented in Number (%) and Mean \pm SD.

RESULTS

The present study revealed that majority (56%) of Henioplasty patients belonged to less than 40 years of age. Age range being 20-86 years while Mean age being 41.95 SD15.07 and majority of patients had Right sided hernia.

Table 1: Pre-operative scores of Components of CCS (n=100)

SN	Question	0	1	2	3	4	5
1a-	Mesh Sens. Lying down						
1b-	Pain Lying down	67	24	9	0	0	0
2a-	Mesh Sens. Bending						
2b-	Pain Bending	0	41	39	16	4	0
2c-	Mov. Limitation Bending	15	41	40	4	0	0
3a-	Mesh Sens. Sitting						
3b-	Pain Sitting	10	36	29	25	0	0
3c-	Mov. Limitation Sitting	31	39	19	11	0	0
4a-	Mesh Sens. Daily activity						
4b-	Pain Daily activity	5	10	71	14	0	0
4c-	Mov. Limitation Daily act.	10	65	25	0	0	0
5a-	Mesh Sens. Cough						
5b-	Pain Cough	0	0	10	75	15	0
5c-	Mov. Limitation Cough	0	10	62	23	5	0
6a-	Mesh Sens. Walk						
6b-	Pain Walk	0	5	44	42	9	0
6с-	Mov. Limitation Walk	5	45	30	16	4	0
7a-	Mesh Sens. Stair movement						
7b-	Pain Stair movement	0	0	10	39	51	0
7c-	Mov. Limitation Stair mov.	0	10	38	52	0	0
8a-	Mesh Sens. Exercise						
8b-	Pain Exercise	0	0	0	29	71	0
8c-	Mov. Limitation Exercise	0	0	15	56	29	0

Table 2: Scores of Components of CCS at 1 month follow up (n=100)

SN	Question	0	1	2	3	4	5
1a-	Mesh Sens. Lying	62	33	5	0	0	0
1b-	Pain Lying	81	19	0	0	0	0
2a-	Mesh Sens. Bending	0	75	25	0	0	0
2b-	Pain Bending	16	70	14	0	0	0
2c-	Mov. Lim Bending	86	14	0	0	0	0
3a-	Mesh Sens. Sitting	5	80	15	0	0	0
3b-	Pain Sitting	51	40	9	0	0	0
3c-	Mov. Lim Sitting	91	9	0	0	0	0
4a-	Mesh Sens. Daily act.	0	87	13	0	0	0
4b-	Pain Daily act.	30	70	0	0	0	0
4c-	Mov. Lim Daily act	90	10	0	0	0	0
5a-	Mesh Sens. Cough	0	0	80	20	0	0
5b-	Pain Cough	0	71	29	0	0	0
5c-	Mov. Lim Cough	68	32	0	0	0	0
6a-	Mesh Sens. Walk	0	66	29	5	0	0
6b-	Pain Walk	52	43	5	0	0	0
6c-	Mov. Lim Walk	90	10	0	0	0	0
7a-	Mesh Sens. Stair movement	13	72	15	0	0	0
7b-	Pain Stair movement	9	76	15	0	0	0
7c-	Mov. Lim Stair mov.	65	30	5	0	0	0
8a-	Mesh Sens. Exercise	0	0	44	46	10	0
8b-	Pain Exercise	0	28	57	10	5	0
8c-	Mov. Lim. Exercise	15	61	19	5	0	0

Pre -Op. Assessment of CCS (Table-1) did not include Mesh sensation score, which was covered in follow up at 1 month (Table-2). Range of CCS score at 1 month was 10 to 37. Mean CCS score being 21.69 SD 6.85. At 6 month (Table-3) follow- up range was 1 to 9, mean being 4.90 SD 2.28.

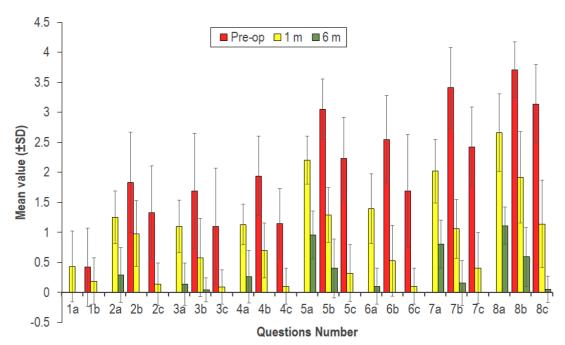
Table 3: Scores of Components of CCS at 6 month follow up (n=100)

SN	Question	0	1	2	3	4	5
1a-	Mesh Sens. Lying	100	0	0	0	0	0
1b-	Pain Lying	100	0	0	0	0	0
2a-	Mesh Sens. Bending	71	29	0	0	0	0
2b-	Pain Bending	100	0	0	0	0	0
2c-	Mov. Lim Bending	100	0	0	0	0	0
3a-	Mesh Sens. Sitting	86	14	0	0	0	0
3b-	Pain Sitting	96	4	0	0	0	0
3c-	Mov. Lim Sitting	100	0	0	0	0	0
4a-	Mesh Sens. Daily act.	74	26	0	0	0	0
4b-	Pain Daily act.	100	0	0	0	0	0
4c-	Mov. Lim Daily act	100	0	0	0	0	0
5a-	Mesh Sens. Cough	10	84	6	0	0	0
5b-	Pain Cough	60	40	0	0	0	0
5c-	Mov. Lim Cough	100	0	0	0	0	0
6a-	Mesh Sens. Walk	90	10	0	0	0	0
6b-	Pain Walk	100	0	0	0	0	0
6c-	Mov. Lim Walk	100	0	0	0	0	0
7a-	Mesh Sens. Stair movement	20	80	0	0	0	0
7b-	Pain Stair movement	84	16	0	0	0	0
7c-	Mov. Lim Stair mov.	100	0	0	0	0	0
8a-	Mesh Sens. Exercise	89	11	0	0	0	0
8b-	Pain Exercise	41	59	0	0	0	0
8c-	Mov. Lim. Exercise	95	5	0	0	0	0

Table 4: Pre-op and at follow up (1 month & 6 month) CCS Score for individual parameters (Question wise)

Q Pre-op]	l month		6 month			
No.	Med	Mn	SD	Med	Mn	SD	Med	Mn	SD
1a				0.00	0.43	0.59	0.00	0.00	0.00
1b	0.00	0.42	0.65	0.00	0.19	0.39	0.00	0.00	0.00
2a				1.00	1.25	0.44	0.00	0.29	0.46
2b	2.00	1.83	0.84	1.00	0.98	0.55	0.00	0.00	0.00
2c	1.00	1.33	0.78	0.00	0.14	0.35	0.00	0.00	0.00
3a				1.00	1.10	0.44	0.00	0.14	0.35
3b	2.00	1.69	0.96	0.00	0.58	0.65	0.00	0.04	0.20
3c	1.00	1.10	0.97	0.00	0.09	0.29	0.00	0.00	0.00
4a				1.00	1.13	0.34	0.00	0.26	0.44
4b	2.00	1.94	0.66	1.00	0.70	0.46	0.00	0.00	0.00
4c	1.00	1.15	0.58	0.00	0.10	0.30	0.00	0.00	0.00
5a				2.00	2.20	0.40	1.00	0.96	0.40
5b	3.00	3.05	0.50	1.00	1.29	0.46	0.00	0.40	0.49
5c	2.00	2.23	0.69	0.00	0.32	0.47	0.00	0.00	0.00
6a				1.00	1.39	0.58	0.00	0.10	0.30
6b	3.00	2.55	0.73	0.00	0.53	0.59	0.00	0.00	0.00
6c	1.50	1.69	0.94	0.00	0.10	0.30	0.00	0.00	0.00
7a				2.00	2.02	0.53	1.00	0.80	0.40
7b	4.00	3.41	0.67	1.00	1.06	0.49	0.00	0.16	0.37
7c	3.00	2.42	0.67	0.00	0.40	0.59	0.00	0.00	0.00
8a				3.00	2.66	0.65	1.00	1.11	0.31
8b	4.00	3.71	0.46	2.00	1.92	0.76	1.00	0.59	0.49
8c	3.00	3.14	0.65	1.00	1.14	0.73	0.00	0.05	0.22

Figure 1: Pre-op and follow up CCS score for individual parameters



Mean CCS score pre-operatively ranged from 0.42 SD 0.65 to 3.71 SD 0.46. Animprovement in scores was observed in scores by end of follow-up at 6 months post-operatively (Figure-1).

Table 5: Statistical Significance of Change in Components of CCS Score(Wilcoxon Signed Rank test)

SN	Question	Preop – 1m		Pre-op – 6m		1m – 6m	
		Z	ʻp'	Z	ʻp'	Z	ʻp'
1a-	Mesh Sens. Lying					5.855	< 0.001
1b-	Pain Lying	4.796	< 0.001	5.273	< 0.001	4.359	< 0.001
2a-	Mesh Sens. Bending					9.211	< 0.001
2b-	Pain Bending	7.756	< 0.001	8.827	< 0.001	8.600	< 0.001
2c-	Mov. Lim Bending	8.298	< 0.001	8.229	< 0.001	3.742	< 0.001
3a-	Mesh Sens. Sitting					9.211	< 0.001
3b-	Pain Sitting	8.030	< 0.001	8.369	< 0.001	6.711	< 0.001
3c-	Mov. Lim Sitting	7.467	< 0.001	7.408	< 0.001	3.000	0.003
4a-	Mesh Sens. Daily act.					8.518	< 0.001
4b-	Pain Daily act.	8.869	< 0.001	8.940	< 0.001	8.367	< 0.001
4c-	Mov. Lim Daily act	8.901	< 0.001	8.674	< 0.001	8.905	< 0.001
5a-	Mesh Sens. Cough					9.210	< 0.001
5b-	Pain Cough	9.210	< 0.001	9.042	< 0.001	8.445	< 0.001
5c-	Mov. Lim Cough	8.905	< 0.001	8.964	< 0.001	5.657	< 0.001
6a-	Mesh Sens. Walk					8.855	< 0.001
6b-	Pain Walk	8.807	< 0.001	8.858	< 0.001	6.637	< 0.001
6с-	Mov. Lim Walk	8.656	< 0.001	8.615	< 0.001	3.162	0.002
7a-	Mesh Sens. Stair movement					8.702	< 0.001
7b-	Pain Stair movement	8.948	< 0.001	8.916	< 0.001	8.980	< 0.001
7c-	Mov. Lim Stair mov.	8.920	< 0.001	8.900	< 0.001	5.601	< 0.001
8a-	Mesh Sens. Exercise					8.611	< 0.001
8b-	Pain Exercise	8.709	< 0.001	9.053	< 0.001	8.031	< 0.001
8c-	Mov. Lim. Exercise	9.002	< 0.001	8.864	< 0.001	8.517	< 0.001

Significant decline in Pre-op CCS (all the components except mesh sensation) in all the eight situations was observed along with decline in Mesh sensation and rest of the variables at 1m and 6m follow up which was also significant.

Table 6: Assessment of change in Overall CCS Score

Time	Mean	SD	Change from Pre-op. (Paired 't' test)						
			Mean	SD	% Ch.	't'	ʻp'		
Pre-op	31.41	8.40							
1 month	21.69	6.85	-9.72	5.72	30.95	-16.990	<0.001		
6 month	4.90	2.28	-26.51	6.75	84.4	-39.255	<0.001		

Decline in pre-Op. CCS score was observed at 1 month and 6 months which were found to be significant statistically. Change in CCS between 1month and 6 months (Table-6) 16.79±5.86 (% change 77.41%) (t=-28.648; p<0.001).

Table 7: Assessment of Components of SF-36 (Pre-op and follow ups)

SN		Pre-	op.	1m post-	op	6m post-	-op
		Mean	SD	Mean	SD	Mean	SD
P1-	General health	41.60	10.12	79.25	4.63	97.30	6.25
P2-	Limitation of activities	23.50	19.73	66.00	39.17	100.00	0.00
Р3-	Physical health problems	61.09	31.64	82.00	28.21	100.00	0.00
P4-	Emotional health problems	53.10	6.73	73.20	5.84	77.55	5.71
P5-	Social activities	59.84	6.70	73.80	4.70	77.60	5.54
P6-	Pain	64.50	10.16	78.13	11.29	92.50	8.88
P7-	Energy & Emotions	52.80	10.46	65.83	11.76	92.60	8.06
P8-	Social activities	29.90	6.47	54.80	11.10	73.80	8.59
	Total	386.33	70.53	573.00	91.68	711.35	30.91

In all the components of SF-36 significant increment in pre- operative scores was observed at 1 month and at 6 months. At 1 month (Table-7) percentage change in pre-op. scores ranged from 21.12% to 180.85% for different parameters. At 6 months percentage change in pre-op. scores ranged from 29.68% to 325.53 for different parameters.

Both CCS and SF-36 were administered to all the patients, after administration of above tools patients were asked to evaluate both the tools for liking of questionnaire, Ease of understanding, reflecting problems with mesh, preference to fill in, if given chance. Vast majority of patients responded in favour of CCS for all the responses (94% to 100%). SF-36 do not deal with specific problem of mesh sensation hence none of the patient responded in favour of SF-36 for question dealing with mesh sensation. However, 6 (6.0%) patients preferred to fill in SF-36.

For validation of CCS, correlation between Overall CCS score and SF-36 score was done.

Table 8: Correlation of CCS and SF-36 at different time intervals

SN	Time	۲°,	Level of correlation	'p'	Level of significance
1-	Pre-operative	-0.376	Mild	<0.001	Highly significant
2-	1 month	-0.126	Poor	0.210	Non-significant
3-	6 months	-0.387	Mild	<0.001	Highly significant

Inverse correlation was found between CCS and SF-36 at all the periods of observation (Pre-op, 1 month & 6 months). Mild and significant correlation between CCS and SF-36 was observed at pre-op and follow up at 6 month (Table-8).

DISCUSSION

Open mesh hernioplasty is the most common procedure for management of inguinal hernia. The method of Lichstentein hernia repair is simple and safe. However, mesh prosthesis has its drawbacks because mesh works as a mechanical barrier and does not give mobile and physiologically dynamic posterior wall [12]. The synthetic prostheses can create new clinical problems, such as foreign body sensation in the groin, discomfort and abdominal wall stiffness, which may affect the everyday functioning of the patient [13]. Moreover, complications like mesh migration, surgical site infection, development of meshoma or plugoma tumors [14-16] are frequent long-term complications. The most common reason being the synthetic nature of the mesh.

Another interesting aspect for research following surgical repair of hernia is the assessment of Quality of Life. While contemporary studies have evaluated the QoL post-herniorrhaphy, the wide variety of surgical managements, changing material and methods have resulted in no strong consensus with respect to QoL post-herniorrhaphy.

The present study was planned to tackle some of the problems associated with the use of CCS and aimed to estimate changes in QoL of patients undergoing Open Mesh hernioplasty using CCS and SF-36 and to validate CCS with SF-36. However, the scope of the study was limited to the concurrent validity between the scales.

For this purpose, 100 individuals fulfilling the inclusion and exclusion criteria were included in the study. The age of these patients ranged between 20to 86 years (Mean age : 41.96 SD 15.07 years). **Majority** (56.0%) of patients were young ≤40 years, all were men (100.0%) and Right sided Inguinal hernia was more common (74.0%). The demography of present study was similar to most of the contemporary studies, however as most of the studies have validated modified CCS in their region and used larger sample sizes and different hernias, that were treated with different methods also, some variationscan be found.

It is also important to note that CCS score and SF-36 both assess QoL and can be self-administered or over tele/electronic channels, moreover, as they assess QoL among adults, the demographic parameters have a limited impacton the assessment. Though, it can be argued that younger population mighthave a higher degree of pain tolerance than elderly population, it can be said that the effects of such a tolerance can be balanced by the fact that both the scales measure a wide variety of parameters affecting daily life. One of the limitations of the present study was that patients with only Inguinal hernia were included and this resulted in exclusion of a large population.

In the present study, CCS administration at pre-operative interval found that overall CCS score ranged between 14 and 49. Mean CCS score was 31.41 SD 8.40 (Median: 30). While, at 1-month post-op. it ranged between 10 and 37 mean being 21.69 SD 6.85 (Median: 20). At 6-months post-op. overall CCS score ranged between 1 and 9, mean CCS score being 4.90 SD 2.28 (Median: 4.90). Significant improvement was also observed in CCS score at 1 & 6-months post-op. for all parameters, as well as, for overall CCS score.

The findings of present study with respect to CCS score were similar to findings of most of the contemporary studies. It has been reported that CCS scores improved significantly over 3-months post-operatively [17]. Similarly, it was reported that CCS scores improved significantly from pre-operative interval to 2 & 6 weeks

post-operatively [18] It was also reported that mean CCS score at week 6 was 0.14 and a significant improvement was observed as compared to week-2 [19].

A significant improvement in QoL among populations was observed at vaious post-operative intervals [20,21]. However, some of the contemporary studies have also reported the problems or complications during the post-operative intervals, these were beyond the scope of the present study.

In the present study, all components of SF-36 improved overtime at 1 & 6 months post-operative interval as seen in Table-8. At both the post-operative interval, a significant improvement of SF-36 was observed as compared to pre-operative interval. These findings were similar to the most of the contemporary literature. It was reported that SF-36 improved significantly at post - operative intervals[22,23].

In the present study, most of patients found the CCS as compared to SF- 36 to be likeable ($94.0\% \ vs. 6.0\%$), easy to understand ($98.0\% \ vs. 2.0\%$), preference to fill in if given a choice ($94.0\% \ vs. 6.0\%$) and more reflective of problems of mesh ($100.0\% \ vs. 0.0\%$). For assessment of concurrent validity between CCS and SF- 36, two scales were correlated and an inverse and mild correlation was observed between the two at pre-op and 6 months follow-up, while a poor correlation was observed at 1-month post-operative interval.

The findings of the present study are noteworthy and novel, especially because of lack of similar studies in India. The study establishes that though, SF-36 is a regularly used QoL assessment tool in India, the world is quickly adapting CCS. The overwhelming response from the patients in favour of CCS is a very important factor when considering QoL on the whole

CONCLUSION

As vast majority (94-100%) of patients preferred CCS over SF-36 for liking of questions, ease of understanding and for reflecting problems with mesh, it can be said that CCS can be used to assess the quality of life of Inguinal Hernia patients, as preferred choice, compared to SF - 36; being more patient friendly and capable of dealing with specific problem (mesh sensation) of Hernioplastypatients.

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