NCGC National Clinical Guideline Centre

Crohn's disease

Appendix O

Clinical Guideline <...>

Stricture management data

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1 Observational data for stricture management

Healthcare professionals seeking to discuss options relating to surgery or balloon dilation for stricture with people with Crohn's disease may find these observational data useful.

1.1.1 Efficacy and safety of balloon dilatation (NR - not reported)

Author Country	Study Period	No. of CD patients ITT	Average (mean) follow-up (months)	Success rate patients (%)	Major Complications (%)*	Need for re-intervention (%) in total sample	Need for re-intervention (%) in successfully dilated sample	Stricture recurrence (%)	Need for surgery (%) in total sample	Need for surgery (%) in successfully dilated sample	Quality of life
Dear et al[8] UK	1992-1999	22	45	22/22 (100)	0/22 (0)	10/22 (45.5)	NR**	NR	6/22 (27.3)	NR	NR
Fukumoto et al[14] Japan	2000-2005	23	11.9	17/23 (73.99)	0/23 (0)	NR	4/23 (17)	NR	NR	2/23 (8.6)	NR
Foster et al[13] USA	1996-2005	24 Glucocorticosteroid use to augment procedure In 14 of 24 people (58.6%)	25.6	24/24 (100)	2/24 (8)	13/24 (54.2)	NR	NR	2/24 (8.3)	NR	NR
Hirai et al[18] Japan	2005-2007	25	6	18/25 (72)	1/25 (4)	6/25 (22.2)	NR	NR	5/25 (20)	NR	NR
Stienecker et al[34] Germany	1997-2007	25	81	20/25 (80)	1/25 (4)	7/25 (28)	NR	NR	4/25 (16)	NR	NR
Hoffman et al[19] Germany	2001-2006	27	17	25/27 (92.6)	1/27 (4)	NR	13/27 (48)		6/27 (24)	6/27 (24 overall) 4/27 (16 due to stricture)	NR
Blomberg et al [4]	1987-	27	19	27/27	4/27 (14)	4/27 (14)	NR	33	8/27		NR

Author Country	Study Period	No. of CD patients ITT	Average (mean) follow-up (months)	Success rate patients (%)	Major Complications (%)*	Need for re-intervention (%) in total sample	Need for re-intervention (%) in successfully dilated sample	Stricture recurrence (%)	Need for surgery (%) in total sample	Need for surgery (%) in successfully dilated sample	Quality of life
Sweden	1989			(100 with tempor-ary effect)					(29.6)		
Nguyen-Tang et al[27] Switzerland	1996-2004	27 (Survey response rate 87%)	47	NR	NR	NR	NR	NR	NR	NR	GIQLI Health related quality of life was significantly impaired in balloon dilatation patients vs. surgical controls and healthy participants (p = 0.005). Impaired categori

Author Country	Study Period	No. of CD patients ITT	Average (mean) follow-up (months)	Success rate patients (%)	Major Complications (%)*	Need for re-intervention (%) in total sample	Need for re-intervention (%) in successfully dilated sample	Stricture recurrence (%)	Need for surgery (%) in total sample	Need for surgery (%) in successfully dilated sample	Quality of life
											es included GI symptoms ($p < 0.001$) and stress by treatment ($p < 0.05$).
Ajlouni et al[1] Australia	1993-2005	37	29 (median)	31/37 (84)	1/37 (3)	8/37 (22)	10/37 (26)	26	4/37 (12)	2/37 (6.5)	NR
Sabate et al [30] France	1991-2000	38	22.8	32/38 (84)	1/38 (2)	NR	14/38 (37.5)	36 at 1 year 44 at 2 years 60 at 5 years	15/38 (39.5)	10/38 (26 at 1 year) 14/38 (38 at 2 years) 16/38 (43 at 5 years)	NR
Morini et al[25] Italy	1988-2001	43	63.7	33/43 (76)	0/43 (0)	31/43 (72.1)	28/43 (64.7)	NR	NR	20/43 (47)	NR
Ferlitsch et al [12] Austria	1993-2003	46	21 (median)	39/46 (84)	4/46 (7.6)	NR	14/46 (31)			13/46 (28 resection) 1/46 (3 stent)	NR
Couckuyt et al [7] Belgium	1989-1992	55	33.6		6/55 (11)	35/55 (63.6)	NR	NR	19/55 (34.5)	NR	NR

Author Country	Study Period	No. of CD patients ITT	Average (mean) follow-up (months)	Success rate patients (%)	Major Complications (%)*	Need for re-intervention (%) in total sample	Need for re-intervention (%) in successfully dilated sample	Stricture recurrence (%)	Need for surgery (%) in total sample	Need for surgery (%) in successfully dilated sample	Quality of life
Matsui et al[22] Japan	1989-1999	55	37	46/55 (83)	1/55 (1.8)	30/55 (55)	30/55 (55)	NR	NR	12/55 (22.5)	NR
Muller et al[26] Germany	1999-2008	55	44	52/55 (95)	1/55 (1.8)	26/55 (47)	NR	NR	13/55 (24)	NR	NR
Thomas-Gibson et al[35] UK	1983-1999	59	29.4 (median)	53/59 (82)	2/59 (3)	48/59 (81)	NR	NR	35/59 (59)	NR	NR
Matsui et al[23] Japan	1992-2002	60	55.2	50/60 (83.3)	2/60 (3.3)	NR	NR	NR	NR	19/60 (32)	NR
Blomberg[3] Sweden	1967-1992	73	Not stated	63/73 (86)	9/73 (12)	NR	NR	NR	NR	NR	NR
Van Assche et al[38] Belgium	1995-2006	138	69.6	134/138 (97)	7/138 (5)	63/138 (46)	NR	NR	33/138 (24)	NR	NR
Summary		859		686/777 88.3%	43/832 5.2%	281/565 49.7%	137/278 49.3%	34% at mean ≤ 3 years; 40% at mean ≤ 5 years	150/632 23.7%	72/269 27% at mean ≤ 5 years	N/A

1.1.2 Time to recurrence – balloon dilatation (NR-not reported)

Study	Time to recurrence	Time to reoperation
Ajlouni (2006)[1]	NR	Median time to recurrent symptomatic stricture requiring dilation or surgery 8 months (7-112 months)
Blomberg (1992)[3]	Symptom relief 'lasting from a few days to well over two years'	NR
Blomberg (1991)[4]	NR	NR
Couckuyt (1995)[7]	Data presented as Kaplan-Meier curve – 50% remained symptom free at 16 months. At 5 years 30% were symptom-free.	Second dilation mean time interval of 1.5 years
Gevers (1994)[16]	NR	NR
Dear (2001)[8]	NR	NR
Ferlitsch (2006)[12]	NR	Median 6 months (1-98)
Foster (2008)[13]	NR	Median time between dilations 3 months (1-40 months)
Fukumoto (2007)[14]	NR	NR
Hirai (2010)[18]	NR	Mean time to surgery 10.4 months after dilation
Hoffmann (2008)[19]	NR	Median time to re-dilation 11 months (2-38 months)
Matsui (2004)[23]	NR	NR
Matsui (2000)[22]	NR	NR
Morini (2003)[25]	Median symptomatic relief 88 months (20-168)	Median interval between first dilation and surgical procedure 21.5 months (10-142 months)
Mueller (2009)[26]	NR	Median time to surgery 1.5 months (0-20 months)
Nguyen-Tang (2008)[27]	NR	NR
Sabate (2003)[30]	Data presented as Kaplan-Meier curve – 50% remained symptom-free at 29 months; 36% remained symptom-free at 5 years.	Median interval between first and second dilations 4.7 months (1-14 months)
Stienecker (2009)[34]	Mean stricture relapse time after successful dilation 32 months (3-77 months)	NR
Thomas-Gibson (2003)[35]	NR	Median time to surgery 4.9 months post-dilation
Van Assche (2010)[38]	NR	Median time to new dilation or surgery after first dilation 12.5 months (6-21.5 months)

1.1.3 Efficacy of surgical treatment for stricture (NR – not reported)

Study	Study period	No of patients	Median* or mean follow-up (mo)	Site of Surgery (includes multiple surgeries for stricture in study population)				Symptomatic recurrence	Reoperation for recurrence
				Jejunum Ileum	Previous anastomosis	Duodenum	Large bowel		
Quandalle et al. (1994)[29] Lille, France	1985-1991	22	36 (12-90)	103	2	2	0	9/22	5/22
Michelassi & Upadhyay (2004)[24] Chicago, USA	1992-2003	30	N/A	28	0	0	3	N/A	7/30
Tonelli et al. (2004)[36] Florence, Italy	1996-2002	31	28 (3-74)	87	0	0	0	N/A	6/31
Spencer et al. (1994)[33] Mayo, USA	1985-1991	35	36	NR	NR	NR	NR	7/35	6/35
Serra et al. (1995)[32] Toronto, Canada	1985-1994	43	54.5 (4-108)	149	3	2	0	17/43	14/43
Yamamoto et al. (1999)[40] Birmingham, UK	1980-1997	111	107*(3-206)	258	27	0	0	20/111	10/111
Tonelli & Ficari (2000)[37] Florence, Italy	1981-1996	44	50	166	7	1	0	N/A	7/44
Hurst & Michelassi (1998)[21] Chicago, USA	1989-1997	57	38 (3-95)	99	9	0	1	N/A	16/57
Broering et al. (2001)[5] Hamburg, Germany	1987-1996	58	70*	0	21	0	52	N/A	24/58
Broering et al. (2001)[6] Hamburg, Germany	1987-1996	67	53* (12-118) 106* (12-126)	103	12	4	0	18/67	13/67
Baba & Nakai (1995) [2] Multi-centre, Japan	N/A	69	37 (0-133)	NR	NR	NR	NR	N/A	18/69
Greenstein et al. (2009)[17] New York, USA	1984-2004	88	82.8	315	10	0	14	N/A	52/88
Fearnhead et al. (2006)[11] Oxford, UK	1978-2003	100	85.1	477	0	0	2	N/A	45/100

Study	**Study period**	**No of patients**	**Median* or mean follow-up (mo)**	**Site of Surgery (includes multiple surgeries for stricture in study population)**				**Symptomatic recurrence**	**Reoperation for recurrence**
Futami & Arima (2005)[15] Fukuoaka, Japan	1989-2002	103	80.3 (12-187)	271	11	2	4	60/103	49/103
Dietz et al. (2001)[10] Cleveland, USA	1984-1999	314	90*	1096	28	0	0	N/A	116/314
Sampietro et al. (2009)[31] Milan, Italy	1993-2007	393	62 (23-101)	327	0	66	0	N/A	67/393
Study	Study period	No of patients	Median* or Mean Follow-up (mo)	Site of Surgery				Symptomatic recurrence	Reoperation for recurrence
				Jejunum/ Ileum	Previous Anastomosis	Duodenum	Large bowel		
Totals		1565	0-206 months	3479	130	77	76	131/381 (34%)	455/1565 (29%)

1.1.4 Safety of surgery for stricture – complications

Study	Study period	No of patients	Overall complications	Sepsis (fistula, abscess, leak)	Haemorrhage*	Ileus	Wound infection	Obstruction	Other	Mortality
Quandalle et al. (1994)[29] Lille	1985-1991	22	1	1	0	0	0	0	0	0
Michelassi & Upadhyay (2004)[24] Chicago	1992-2003	30	3	1	1	0	0	0	0	1
Tonelli et al. (2004)[36] Florence	1996-2002	31	6	0	1	0	0	0	5	0
Spencer et al. (1994)[33] Mayo	1985-1991	35	5	0	0	0	2	2	1	0
Serra et al. (1995)[32] Toronto	1985-1994	43	7	1	1	0	5	0	0	0
Tonelli & Ficari (2000)[37] Florence	1981-1996	44	3	0	1	0	0	2	0	0
Hurst & Michelassi (1998)[21] Chicago	1989-1997	57	7	1	1	2	0	3	0	0
Broering et al. (2001)[5] Hamburg	1987-1996	58	13	2	2	1	4	2	2	0
Broering et al. (2001)[6] Hamburg	1987-1996	67	12	0	6	0	5	1	0	0
Baba & Nakai (1995)[2] Japan	N/A	69	3	1	0	0	1	1	0	0
Greenstein et al. (2009)[17] New York	1984-2004	88	9	2	0	3	4	0	0	0
Fearnhead et al. (2006)[11] Oxford	1978-2003	100	27	11	4	0	0	4	5	3
Futami & Arima (2005)[15] Fukuoka, Japan	1989-2002	103	11	7	1	2	0	0	1	0
Yamamoto et al. (1999)[39] Birmingham	1980-1997	111	24	8	2	4	6	0	4	0

Study	Study period	No of patients	Overall complications	Sepsis (fistula, abscess, leak)	Haemorrhage*	Ileus	Wound infection	Obstruction	Other	Mortality
Dietz et al. (2001)[10] Cleveland	1984-1999	314	57	13	23	14	4	3	0	0
Sampietro et al. (2009)[31] Milan	1993-2007	393	22	15	5	2	0	0	0	0
Study	Study period	No of patients	Overall complications	Sepsis (fistula, abscess, leak)	Haemorrhage*	Ileus	Wound infection	Obstruction	Other	Mortality
Totals		1565	210/1565 (13%)	63/1565 (4%)	48/1565 (3%)	28/1565 (1.8%)	31/1565 (2%)	18/1565 (1%)	18/1565 (1%)	4/1565 (0.26%)

1.1.5 Time to recurrence – surgery for stricture (NR – not reported)

Study	Time to recurrence	Time to reoperation
Baba (1995)[2]	NR	NR
Broering (2001) [5] – large bowel	Mean time to recurrence after strictureplasty 26.6 months, after resection 33.5 months	NR
Broering (2001) [6] – small bowel	Mean time to recurrence after strictureplasty 16 ± 14 months, after resection 34 ± 19 months	NR
Di Abriola (2003)[9]	NR	NR
Dietz (2001)[10]	NR	Data presented as Kaplan-Meier curve – 20% reoperation at 5 years; 50% reoperation at 10 years
Fearnhead (2006)[11]	NR	Mean time to reoperation 34.3 months (0.2-205.8 months)
Futami (2005)[15]	NR	Data presented as Kaplan-Meier curve – 45% reoperation at 5 years; 62 % reoperation at 10 years.
Greenstein (2008)[17]	NR	20 % (CI 12-28%)at 5 years and 38% (CI 26-50%)at 10 years
Hurst (1998)[20]	NR	Mean time to surgical recurrence 30 months (10-67 months)
Michelassi (2004)[24]	NR	Mean time to reoperation 53 months (13-98 months)
Oliva (1994)[28]	Mean time to exacerbation 7.5 months	NR
Quandalle (1994)[29]	Median time to symptomatic recurrence 24 months (6-36 months)	NR
Sampietro (2009)[31]	17.1% at 5 years; 33.5% at 10 years	NR
Serra (1995)[32]	NR	Mean time to second surgery 2.4 years
Spencer (1994)[33]	NR	Mean time to re-exploration for obstruction 2.2 years (9 months-3.5 years)
Tonelli (2004)[36]	NR	Mean time to reoperation 44 months (13-60 months)

1.1.6 Quality of life after strictureplasty verses resection: IBDQ

Study	Study period	No of patients	Median follow-up (mo)	Bowel (7-70 points)	Systemic symptoms (5-35 points)	Emotional function (12-84 points)	Social function (5-35 points)	Total/maximum points
Broering et al. (2001) (large bowel)	1987-1996	Strictureplasty = 17 Resection = 25	70 70.5	50 (33-68) 53 (37-70)	24 (12-35) 27 (15-35)	69 (37-84) 69 (31-84)	34 (6-35) 33 (11-35)	177/224 182/224
Broering et al. (2001) (small bowel)	1987-1996	Strictureplasty = 18 Resection = 32	53 (12-118) 106 (12-126)	50 (19-70) 56 (32-70)	24 (7-35) 26 (11-35)	64 (24-84) 67 (31-84)	28 (11-35) 30 (18-35)	167/224 181/224

1.1.7 Paediatric stricture surgery studies

Study	Study period	No of patients	Median or Mean age at surgery	Median* or mean follow-up (mo)	Site of surgery				Early/late complications	Weaned from glucocortico-steroid	Change in PCDAI
					Jejunum/ Ileum	Previous anastomosis	Duodenum	Large bowel			
Oliva et al. (1994)[28]	1987-1992	8	Mean age 16 (10-19)	19 (3-55)	NR	NR	NR	NR	2 (haemorrhage)	83%	NR
Di Abriola et al. (2003)[9]	N/A	5	Mean age 16 (14-20)	22 (6-30)	5	0	0	0	0	100%	-42.5

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