

Included article

A JhfU7]d² ž < H5 fYdcfh&\$%&.)

	Författare, år	Studiedesign	Resultat	Kommentarer	Q
1	Ussia,GP et al. Quality of life following percutaneous mitral valve repair with the MitraClip System. Int J Cardiol, 2012. 155 (2): p. 194-200.	Observational study 49 consecutive pts No control group Functional MR 64%, degenerative MR 36%	6 months follow up in 34 pts improved functional status (from MR+3 or worse to 86% \leq MR 1 and 14%, MR 2) . 5/39 (13%) pts with increased MR. Improvement of QoL (p<0,000, in most QoL variables) Better effect in functional MR pts(!?). NYHA improved in all patients (p<0,001)	Limited no of pts No control group Loss of 10 pts at follow up (5 deaths), PPT-analysis	Low
2	Van den Branden, B.J., et al., Percutaneous edge-to-edge mitral valve repair in high-surgical-risk patients: do we hit the target? JACC Cardiovasc Interv, 2012. 5 (1): p. 105-11.	Observational study 52 consecutive pts Single center study	In hosp mortality 3,8% 48 pts evaluated at 6 months tot 11.5% mortality, 5 pts HF related, 1 pt non cardiac death 12,5% of pts were re hosp MR \leq 2 in 79% of pts after repair (p<0,001) Improvement of LVEDD (p<0,01), LVEF (p<0,05) (42 pts), QoL (p<0,001, 44 pts), 6-MWT (p<0,02, 31 pts) and NT-proBNP (p<0,001, 38 pts) and NYHA (p<0.001, 44 pts) 5 pts (11,4%) did not improve in NYHA	Limited no of pts No control group Loss of pts at follow up Functional MR pts (90%) PPT analysis Long walking distance in 6MWT	Low
3	Whitlow PL et al., Acute and 12-month results with catheter-based mitral valve leaflet repair: the EVEREST II (Endovascular Valve Edge-to-Edge Repair) High Risk Study. J Am Coll Cardiol, 2012. 59 (2): p. 130-9.	Prospective, multi-center single arm study, 78 pts 59% (46/78) functional MR, 41% (32/78) degen MR	30 day mortality, 7,7% 12 months mort 24,4% 78% of pts MR \leq 2 after MitraClip (p<0,0001) Improvement of LVEDV and LVESV (p<0,001)and clinical symptoms NYHA (p<0,0001)) and QoL (p<0,01 physical component, mental componemt n.s.)	EVERESTII,high risk study. Retrospective comparator group,58 identified pts, 36 included, 21 pts met all criteria, 86% medical treatment, 14% MV surgery Rehospitalisation not sign decreased if cardiac death pts is included in calc! No data from pts who later died.	Low
4	Treede, H., et al., A heart team's perspective on interventional mitral valve repair: percutaneous clip implantation as an important adjunct to a surgical mitral valve program for treatment of	Observational study 202 consecutive pts. Functional MR 65%, degen MR 27,mixed 8%.	186 implant (92% succ rate) Hospital stay 12 \pm 10 days. Hospitalization, mean 9 days (range 1-73) during the first year(?) 30 days mortality 3,5%	"Real-life" pts, i e high EuroSCORE 11 pts had open heart surgery No control group Major loss of pts to follow up, echocardiografi in 88 pts (47%) at 12 months	Low

	Författare, år	Studiedesign	Resultat	Kommentarer	Q
	high-risk patients. J Thorac Cardiovasc Surg, 2012. 143 (1): p. 78-84.		Estimated one year mortality 10,4% Improvement of MR grade ($p<0,001$) stable for 12 months, 10 pts (10%) no reduction in MR grade Improvement of NYHA ($p<0,0001$), stable for 12 months.		
5	Auricchio, A., et al., Correction of mitral regurgitation in nonresponders to cardiac resynchronization therapy by MitraClip improves symptoms and promotes reverse remodeling. J Am Coll Cardiol, 2011. 58 (21): p. 2183-9.	Multicenter prospective observational study, 51 unselected pts	Mort 5,8% periprocedural 30 days mort 4,2%, Follow up 8-17 months mean 14 months 12 months mort, 9 pts (18%) At 6 and 12 months, improvement of NYHA ($p<0,001$) and of LVEDD ($p<0,01$), LVESD ($p<0,03$), LVESV ($p<0,03$) LVEDV ($p<0,008$) and LVEF($p<0,0001$) 5 pts hospitalized during the follow up year	Some MR 2 pts (2%) are included No control group 18% loss of pts, 42 pts were evaluated after 12 months	Low
6	Divchev, D., et al., In-Hospital Outcome of Patients with Severe Mitral Valve Regurgitation Classified as Inoperable and Treated with the MitraClip(R) Device. J Interv Cardiol, 2011.	Prospective observational study, the first 33 unselected pats in the heartcentre Functional MR in 23 pts (69,7%), degenerative MR 10 pts (30,3%)	Hospital stay $10\pm 2,7$ days No major adverse events 81,7% improved from MR 3+ to MR ≤ 1 and 12,1% to MR2. ($p<0,0007$) Decreased PAP syst ($p<0,0001$) and PCWP ($p<0,009$) NYHA improved ($p<0,0008$)	No control group Limited no of pts Short observational time Intrahospital outcome	Low
7	Franzen, O., et al., MitraClip(R) therapy in patients with end-stage systolic heart failure. Eur J Heart Fail, 2011. 13 (5): p. 569-76.	Retrospective observational multicenter study (7 centers), 48 pts successfully treated	After MitraClip MR grade below grade 2+ (44 pts), 92% at discharge and 87% after 6 months (31 pts evaluated) 30 day mortality 6% 6 months mortality 18,8% 6 months follow up: NYHA improved ($p<0,000$, 32 pts) At six months 9/32 (28%) had NYHA III/IV 6 MWT (19pts) improvement ($p<0,0005$), very wide variation (median 100m increase, range 10-263 m) MLHFQ improved ($p<0,004$, 16 pts), wide variation NT-proBNP improved ($p<0,005$, 18 pts) 58% (38 pts) were rehospitalized during 6 months	Major loss of pts to follow up (8 pts died, 8 refused follow up) No uniform study protocol	Low

	Författare, år	Studiedesign	Resultat	Kommentarer	Q
8	Rudolph, V., et al., Echocardiographic and clinical outcomes of MitraClip therapy in patients not amenable to surgery. J Am Coll Cardiol, 2011. 58 (21): p. 2190-5.	Prospective observational study 104 unselected consecutive pats, 66% functional, 28% degen, 8% mixed,	96 pts succ MitraClip Follow up at 6 and 12 months 55% of pts had at least one major adverse event In hosp mort 3,8% 26 pts (25%) died between 10-698 days) Rehospitalisation 27% NYHA III/IV was 100% before MitraClip and 31% after MitraClip , 6-MWT (p<0,0005, 55 pts), NT-proBNP (p<0,0288, 52 pts) and MLHFQ (p<0,0009, 47 pts) LVEDV (p<0,0001, 63 pts)LVESV (p<0,0002, 63 pts), LVEF (ns)	Partly same pts as in article no 8?? Major loss of pts to follow up	Low
9	Pleger, S.T., et al., Acute safety and 30-day outcome after percutaneous edge-to-edge repair of mitral regurgitation in very high-risk patients. Am J Cardiol, 2011 108 (10): p. 147-82.	Prospective observational study of 33 pts Functional MR 63%,Degen MR 36%	32 pts evaluated 30 day follow up : no mortality improvement regarding mitral regurgitation (p<0,0001), NYHA (p<0,001) and 6-MWT (p<0,01) NT-proBNP (ns) LVEF, LVEDV and LAV unchanged (ns)	Short follow up "early results" No control group Limited no of pts High coorbidity	Low
10	Feldman, T., et al., Percutaneous repair or surgery for mitral regurgitation. N Engl J Med, 2011. 364 (15): p. 1395-406.	Multicenter study, 279 pts randomized (ratio 2:1) to MitraClip (184 pts) or open convent surgery(95pts)	Major adverse events 15% in MitraClip pts 181 MitraClip pts evaluated after 12 months ITT analyses Mort 6% In MitraClip group MR grade 3 or worse in 21% 30 days mortality 2% Improvement of LVEDV (p<0,001, 144-148 pts), LEVDD, LVESV and LVEF. LVESD (ns) Improvement of QoL (p<0,001, 147 and 132 pts) at 30 days and 12 months resp	Lower risk pts No control group (farm treatment) Major loss of pts at follow up 23% of MitraClip pts to open surgery	Low
11	Franzen, O., et al., Acute outcomes of MitraClip therapy for mitral regurgitation in high-surgical-risk patients: emphasis on adverse valve morphology and severe left ventricular dysfunction. Eur Heart J, 2010. 31 (11): p. 1373-81.	Prospective observational study, 51 consecutive pts Functional 69%, degen 31% Single center	49 implanted Mitraclip No procedure related major adverse events, No in hospital mort, Hospital stay mean 7,1 days. MR grade 3 or worse was treduced from 100% to 6% before and after MitraClip resp Improvement of NYHA (p< 0,0001)	Initial experience No control group Limited no of pts Partly the same pts as in article 8 and 9?	Low

	Författare, år	Studiedesign	Resultat	Kommentarer	Q
12	Tamburino, C., et al., Percutaneous mitral valve repair with the MitraClip system: acute results from a real world setting. Eur Heart J, 2010. 31(11): p. 1382-9	Observational study of 31 pts Functional MR 58%, degen MR 42%	Two site study 30 days follow up Major adverse events in 2 pts NYHA improved from 87% in class III/IV to 100% in class I/II Improvement of LVEDD (p<0,001), LVESD (p<0,001), LVEDV (p<0,001). LVEF (ns). Partly same pts as in article 1?	Limited no of pts No control group Non randomized Single assessor of echocard Low no pts Early outcome, preliminary data	

Excluded article

A JhfU7`jd# ž < H5`fYdcfh&\$%&.)

	Författare, år	Kommentarer
1	<p>Conradi, L., et al., Impact of MitraClip therapy on secondary mitral valve surgery in patients at high surgical risk. Eur J Cardiothorac Surg, 2011. 40(6): p. 1521-6.</p>	<p>Prospective study of 6 pts with failed MitraClip intervention.</p>
2	<p>Gaemperli, O., et al., Acute haemodynamic changes after percutaneous mitral valve repair: relation to mid-term outcomes. Heart, 2012. 98(2): p. 126-32.</p>	<p>Immediate hemodynamic evaluation after MitraClip.</p>
3	<p>Glower, D., et al., EVEREST II randomized clinical trial: Predictors of mitral valve replacement in de novo surgery or after the MitraClip procedure. J Thorac Cardiovasc Surg, 2012. 143(4 Suppl): p. S60-3.</p>	<p>Surgical technical considerations.</p>
4	<p>Grayburn, P.A., et al., Mechanism and severity of mitral regurgitation by transesophageal echocardiography in patients referred for percutaneous valve repair. Am J Cardiol, 2011 108(6): p. 882-7.</p>	<p>Transesophageal echocardiography is helpful in assessment of MR patients.</p>
5	<p>Herrmann, H.C., et al., Effects of atrial fibrillation on treatment of mitral regurgitation in the EVEREST II (Endovascular valve edge-to-edge Repair Study. Randomized Trial. J Am Coll Cardiol 2012. 59(14): p. 1312-9.</p>	<p>Patients included in the EVEREST II study.</p>
6	<p>Schillinger, W., et al., Impact of the learning curve on outcomes after percutaneous mitral valve repair with MitraClip and lessons learned after the first 75 consecutive patients. Eur J Heart Fail, 2011. 13(12): p. 1331-9.</p>	<p>Evaluation of MitraClip intervention at one centre, impact of learning curve.</p>
7	<p>Herrmann, H.C., et al., Effect of percutaneous mitral repair with the MitraClip device on mitral valve area and gradient. EuroIntervention, 2009. 4(4): p. 437-42.</p>	<p>Echocardiography results 24 months after MitraClip in 96 pts.</p>
8	<p>Herrmann, H.C., et al., Mitral valve hemodynamic effects of percutaneous edge-to-edge repair with the MitraClip device for mitral regurgitation. Catheter Cardiovasc Interv, 2006. 68(6): p. 82 1-8.</p>	<p>Echocardiography results before and 12 months after MitraClip in 27 pts.</p>

	Författare, år	Kommentarer
9	Mauri, L., et al., The EVEREST II Trial: design and rationale for a randomized study of the evalve mitraclip system compared with mitral valve surgery for mitral regurgitation. Am Heart J, 2010. 160 (1): p. 23-9.	Describing the rationale and design of the EVEREST II study.
10	Siegel, R.J., et al., The acute hemodynamic effects of MitraClip therapy. J Am Coll Cardiol, 2011. 57 (16): p. 1658-65.	Mix of pts from EVEREST I and II studies.
11	Silvestry, F.E., et al., Echocardiographic guidance and assessment of percutaneous repair for mitral regurgitation with the Evalve MitraClip: lessons learned from EVEREST I. J Am Soc Echocardiogr, 2007. 20 (10): p. 1131-40.	47 first pts enrolled in EVEREST I study. Evaluation of the echocardiography protocol.
12	Feldman, T., et al., Percutaneous mitral valve repair using the edge-to-edge technique: six-month results of the EVEREST Phase I Clinical Trial. J Am Coll Cardiol, 2005. 46 (11): p. 2134-40.	Six months result of the EVEREST I study.
13	Feldman, T., et al., Percutaneous mitral repair with the MitraClip system: safety and midterm durability in the initial EVEREST (Endovascular Valve Edge-to-Edge REpair Study) cohort. J Am Coll Cardiol, 2009. 54 (8): p. 686-94.	Midterm results of the EVEREST study.
14	Van den Branden, B.J., et al., Percutaneous mitral valve repair using the edge-to-edge technique in a high-risk population. Neth Heart J, 2010. 18 (9): p. 437-43.	30 days follow up of initial nine pts at one center.
15	Foster, E., et al., Quantitative assessment of severity of mitral regurgitation by serial echocardiography in a multicenter clinical trial of percutaneous mitral valve repair. Am J Cardiol, 2007. 100 (10): p. 1577-83.	Echocardiographic study at 6 months of 55 pts in the EVEREST study