Hernia repair with 3-D- Meshes - first results of a multicenterstudy with more than 1000 patients

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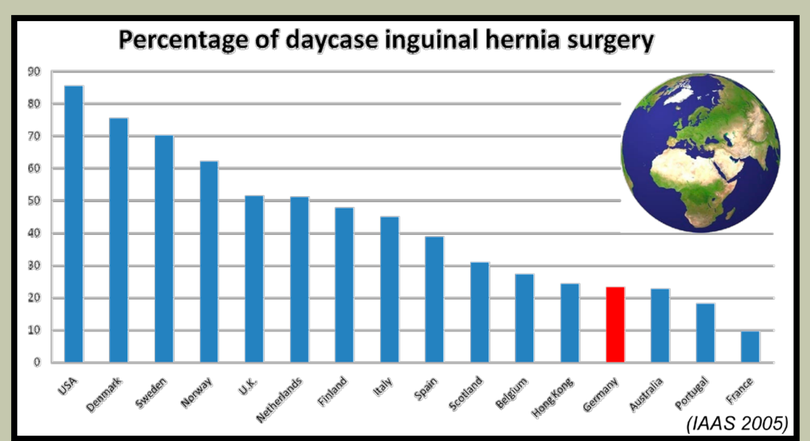
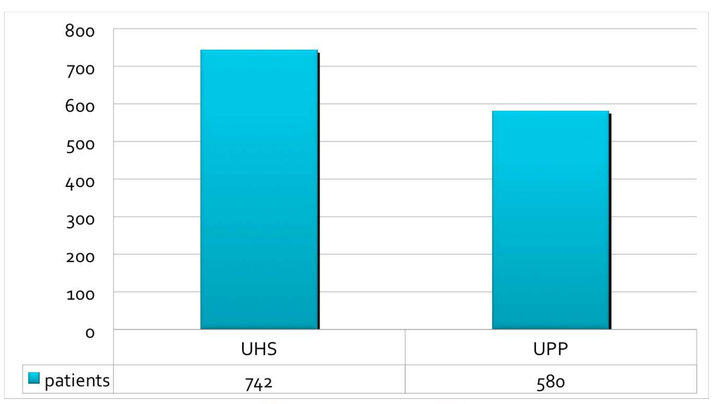
Background: In Germany the health system is strictly separated in an ambulatory and a hospital sector. The percentage of day case Hernia surgery in Germany is very low comparing to the average of the industrial countries - last studies have shown a part of only 20%. The improvement of this part could save a lot of money. Large-scale data for the inguinal hernia repair in an ambulant setting are rare. 15 ambulant centres with expierience using 3 dimensional and partly resorbable Meshes for inguinal hernia surgery initiating an data base for ambulatory hernia surgery. This register was introduced on the 1st of October 2009. We analysed the data after the first more than1000 operations for risk of reoperation and early postoperative results after 4 and 12 weeks including the risk of chronic inguinal pain



Methods: We developed a large prospective multicenter study together with 16 specialized hernia centers in Germany. This could be a first possible step in the development of a country covering database. This study should show that results in the ambulatory sector have an equal high quality like in the hospital sector. Prospective recording of all inguinal hernia repairs using 3 D meshes since 1st October 2009 in a online based Hernia Database (www.qs-leistenhernie.de). Clinical examination 4, 12 weeks after surgery by the surgeon. We are presenting an analysis of the first 1322 cases. There is an continuous registration of all consecutive operations.

Results: There are 1181 males and 141 females. The average age for males and females was 53 years. The average operation time was 38 minutes. There are 1179 primary and 143 recurrent hernias. Nearly 95% (n=1280) of all operations were performed using a general anaesthesia., local anaesthesia in 26 and regional anaesthesia in 11 cases. Ultra Pro Herniasytem (UHS, Gilbert Procedure) was used in 57 % and UPP (Ultra Pro Plug) in 43%. There were 6 infections (0,5%) and 9 early recurrences (0,7%) reported. Sensory disturbance was reported after 4 weeks in 12.4% and after 12 weeks in 4.8%. Inguinal pain was found after 4 weeks in 6.2% and after 12 weeks in 2.3%. Testicular pain after 4 weeks 2.7% and after 12 weeks 0.7%.

Used 3D Meshes



cost savings

„…In the United States most hernia repairs (80-90%) are performed as day surgery procedure; 90% of operations are open herniorrhaphies with mesh.

If in Germany an equal proportion of hernia repair as in the United States would be done as ambulatory procedure (80-90%), there would be an annual cost saving of several hundred million € …“ (Holzheimer 2004)

First Results

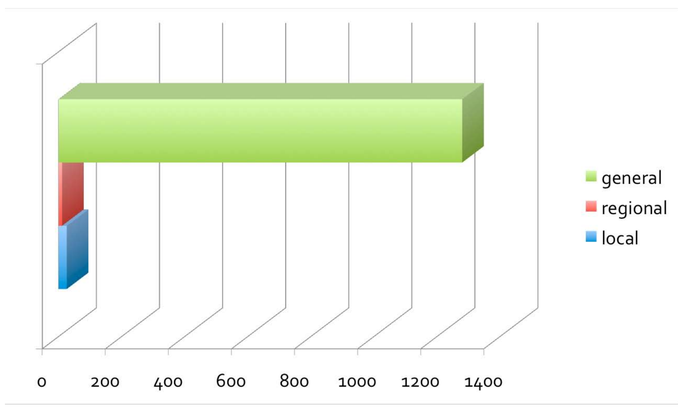
- Start 1.10.2009
- 16 day surgery centers specialized in hernia surgery
- 30.08.2010
  - 1322 Patients enrolled
  - 1181 male (age median 53 ys.)
  - 141 female (age median 53 ys.)

Perioperative Data and Results

- **Day surgery** **n=819 (62%)**
- **Short stay hospital** **n=499 (38%)**

  - Op-time median 38 minutes
  - Primary hernias 1179
  - Recurrent hernias 143
  - 10,8% at all are recurrent hernias !

Anaesthesia



Follow up

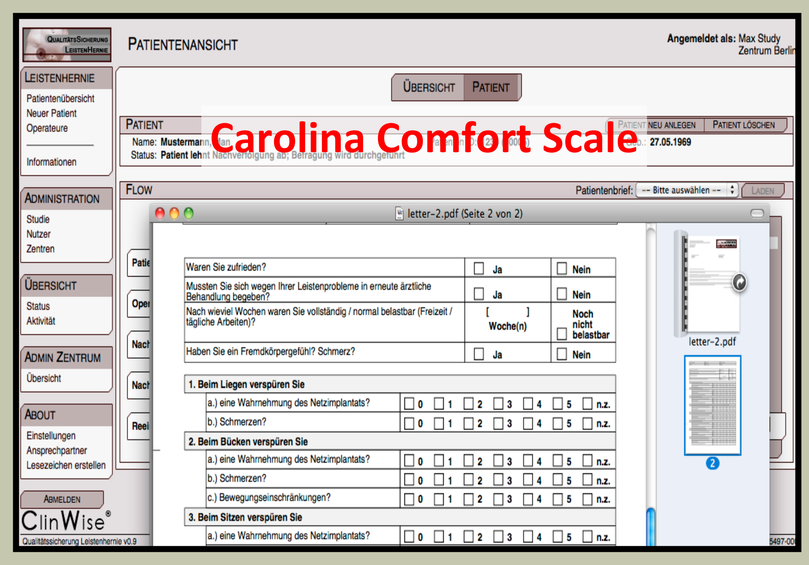
- 1116 complete follow up after 4 weeks
  832 complete follow up after 12 weeks
  (follow up by physician)
- Patients survey (Carolina Comfort Scale):
  - 1222 CCS letters dispatched by mail
  - 822 replyed (67%)

Pilot phase with 16 hernia centers in Germany

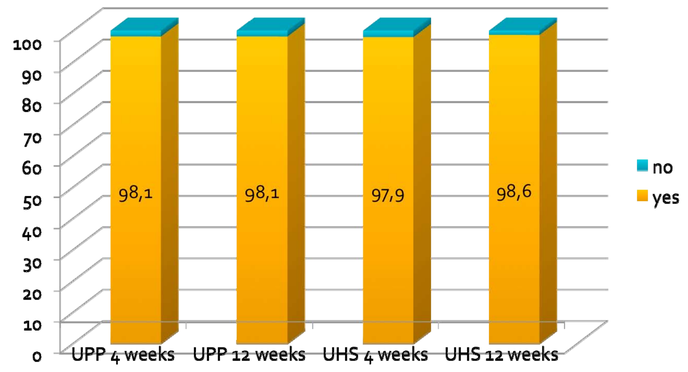
Arnsberg
Berlin
Cottbus
Dortmund
Jena
Kelkheim
Krefeld
Lampertheim
Leipzig
Meißen
München
Münster
Neumünster
Nürnberg
Tübingen

12 weeks follow up

- impairment of inguinal sensibility n=64 (4,8%)
- Testicular pain n=9 (0,7%)
- Inguinal pain n=30 (2,3%)
- Seroma n=7 (0,5 %)
- Recurrence n=9 (0,7%)



Patients Satisfaction 4 and 12 weeks



Conclusion: Although hernia repair with 3 dimensional partly resorbable meshes was not associated with more perioperative complications, and less impairment of inguinal sensibility after 12 weeks. Incidence of pain were comparable or less than other techniques. The ongoing data base is feasible to perform a continuous documentation and quality control in hernia surgery.

Literature: Holzheimer,RG (Halle) Eur J Med Res. 2004 Jun 30;9(6):323-7, International Association for Ambulatory Surgery (IAAS) (2005)