

TAVIは重症大動脈弁狭窄症患者のQOLを改善する

非侵襲的TAVI手術は実地臨床の場において健康関連のQOLを改善する

Minimally invasive TAVI procedure leads to an improvement in health-related quality of life in real world setting

経カテーテルの大動脈弁植え込み術 (TAVI) は、1年以上維持された重症大動脈弁狭窄症患者の健康に関連したQOLを有意に改善するとのスタディ結果が2012年European Society of Cardiology学会で発表された。この前向き多施設German transcatheter aortic valve interventionsレジストリではベースライン、30日後および12か月後の健康関連QOLをEQ-5D質問票を用いて評価した。スタディではTAVI後12か月生存した患者計415人 (平均年齢81.9 ± 5.9歳; 男性37.3%) のQOLデータを使用した。12か月後、TAVI患者はEQ-5Dの各々の面について改善したと報告した。12か月後の時点で通常の活動に問題のない患者の割合は17.5%から48.6%に上昇し、何らかの問題のある患者は72.5%から39.7%に低下し、非常に問題のある患者は10.1%から11.7%にやや増加した。不快感に関しては、問題のない患者の割合は22.7%から61.9%に上昇し、何らかの問題のある患者は69.1%から33.3%に減少し、非常に問題のある患者は8.3%から4.8%に減少した。1年後に患者自身が評価したこのQOLに関する有益性は持続性であった。

Full Text

Transcatheter aortic valve implantation (TAVI) leads to meaningful improvements in health-related quality of life in patients with severe aortic stenosis that are maintained for at least 1 year, according to a study presented at ESC Congress 2012. The results from the German transcatheter aortic valve interventions registry were presented by Professor Till Neumann, M.D., from Essen, Germany.

Aortic stenosis is the most common valvular heart disease with increasing incidence especially with regard to the ageing of the population. Today, the prevalence of aortic stenosis is estimated at about 2.5% of 75 year olds and 8.1% of people aged 85 years.

TAVI, introduced in 2002 by Dr. Alain Cribier from France and 2005 by Dr. John Webb from Canada, has been shown to improve survival compared with standard therapy in patients with severe aortic stenosis who cannot have surgery. In particular, older patients with aortic stenosis cannot always be offered conventional surgical aortic valve replacement at an acceptable risk. As a consequence, about 30% of these patients are presently not operated. Therefore TAVI is currently an alternative treatment option.

The prospective multicenter German transcatheter aortic valve interventions registry includes patients with symptomatic, severe aortic stenosis since January 2009. "The registry was designed to monitor current use and outcome of transcatheter aortic valve interventions, including TAVI, in daily clinical routine, and to evaluate safety, effectiveness and health economic data," said Professor Neumann. "Therefore, the registry gives insight into a real world setting of using the TAVI procedure."

Health-related quality of life was assessed at baseline, at 30 days and 12 months with the EQ-5D questionnaire, a prominent instrument to measure health-related quality of life. The study used quality of life data for a total of 415 patients who survived 12 months after TAVI (average age 81.9 ± 5.9 years; men 37.3%). At 12 months, TAVI patients reported improvements with regard to each single dimension of the EQ-5D. In particular the distribution of the three levels (no problems, some problems, extreme problems) changed with regard to usual activities and discomfort after 12 months.

For usual activities, the proportion of patients with no problems rose from 17.5% to 48.6%, with some problems decreased from 72.5% to 39.7%, and with extreme problems increased slightly from 10.1% to 11.7%. For discomfort, the proportion of patients with no problems rose from 22.7% to 61.9%, with some problems decreased from 69.1% to 33.3%, and with extreme problems decreased from 8.3% to 4.8%. Professor Neumann said: "Patients gain improvements in their usual activities and feel more comfortable."

He added: "One of the main findings of our study is a remarkable increase in patients' self-ratings of quality of life after TAVI." Scores on the visual analogue health scale (EQ VAS), which records the patient's self-rated health on a vertical, visual analogue scale, significantly improved from a mean value of 44.7% ± 16.5 at baseline to 62.9% ± 17.4 at 30 days. However, even more important was the fact that this benefit in quality of life was sustained, as indicated by the patient's self-rated health status after one year (65.1% ± 20.6).

"Our results demonstrate that the minimal invasive procedure of TAVI does not only save lives but also leads to a remarkable improvement in health-related quality of life in a real world setting," said Professor Neumann. "This benefit in quality of life lasts for a long time period."

He continued: "Patients with severe aortic stenosis can profit from TAVI – the gain in health-related quality of life confirms this. Our findings regarding quality of life could give further impetus to the argument for performing TAVI in older patients with severe aortic stenosis."

The German transcatheter aortic valve interventions registry is completely independent from industry. It is driven by the scientific interest of the participating hospitals and advanced by the Institut für Herzinfarktforschung (IHF) in Ludwigshafen, Germany.

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