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Czech TAVI Registry – rationale and design

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ABSTRACT

Aortic stenosis is the most common type of valve disease in the adults. Until recently its treatment was an exclusive domain of cardiac surgery. At the same time the aortic valve replacement (SAVR) was not indicated in about 1/3 of the patients, though the prognosis of conservatively treated patients is very unfavorable with one-year mortality rate of 50%. These facts were the main reasons for starting a new interventional era of the aortic valve disease therapy in 2002 and from 2007 two types of valves fixed in stents have been commercially available.

In the early phase the transcatheter aortic valve implantation (TAVI) was used just in patients with contra-indication to SAVR or with high perioperative risk after surgery. Before applying this therapy to less risky patients some problems have to be solved: 1. clinical impact of the relatively high rate of paravalvular leaks and 2. long-term function of the implanted valve in follow-up exceeding 5 years.

In the Czech Republic the first TAVI was performed in Prague, IKEM in December 2008. During a short period of time the TAVI program was initiated also in other complex cardiovascular centers in Hradec Kralove, Brno, Prague – FN Kralovske Vinohrady and Trinec. Including the later starting centres (Usti n. Labem, Olomouc, Ceske Budejovice and other three centers in Prague – Nemocnice na Homolce, FN Motol and VFN) there is a total of 11 centers providing the TAVI at present. All centers except one (FN Motol) are part of the Czech TAVI Registry that was developed with the support of the Czech Society of Cardiology and started on September 1, 2010. In general and more theoretically there are two parts of the Registry: 1. "Retrospective" including all the TAVI procedures from the beginning of the TAVI program in the Czech Republic that was terminated on June 30, 2011 and 2. "Prospective" that has been following. Institute of Biostatistics and Analyses of Masaryk University takes care of the online and anonymized database.

The results of the national Czech TAVI Registry should help to answer the clinical relevant questions mentioned above.

Klíčová slova:
Nemocní s vysokým operačním rizikem
Registr
Transkatetrová implantace aortální chlopně (TAVI)

SOUHRN

Aortální stenóza je nejčastější chlopenní vadou v dospělosti, jejíž řešení bylo donedávna výlučně spojeno s kardiochirurgickou operací. K náhradě aortální chlopně (SAVR) se však nepřistoupilo u cca jedné třetiny nemocných, přestože tito nemocní mají 50% úmrtnost v průběhu jednoho roku. Tyto závažné skutečnosti výrazně přispěly k rozvoji nové, intervenční éry léčby aortální stenózy, která se datuje od roku 2002 a poté od roku 2007, kdy byly na trh uvedeny dva nové typy perkutánně zaváděných chlopní všitých do stentů.

V počáteční fázi se transkatetrová implantace aortální chlopně (TAVI) prováděla pouze u nemocných s vysokým operačním rizikem nebo kontraindikací k operační náhradě. Před všeobecným přijetím TAVI pro léčbu i méně rizikových nemocných je nutno vyřešit některé problematické otázky, které jsou s tímto výkonem spojené: 1. klinický dopad relativně vysoké přítomnosti paravalvárních leaků a 2. funkce implantované chlopně v dlouhodobém horizontu přesahujícím pětileté sledování.

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V České republice byl program TAVI zahájen prvním výkonem provedeným v Praze, IKEM v prosinci 2008. Krátce poté byly provedeny první výkony také v komplexních kardiovaskulárních centrech v Hradci Králové, v Brně, v Praze ve FN Královské Vinohrady a v Třinci. V současné době se tyto výkony provádějí také v Ústí n. Labem, Olomouci, Českých Budějovicích a v Praze v Nemocnici Na Homolce, ve FN Motol a VFN Praha. Celkem se v České republice TAVI provádí v 11 kardiocentrech, z nichž pouze FN Motol není součástí Czech TAVI Registry. Vznik tohoto registru byl podpořen Českou kardiologickou společností. Pro provedení následných analýz je registr rozdělen na dvě části: 1. „retrospektivní" část zahrnující všechny výkony TAVI od začátku programu TAVI v České republice, která byla ukončena k 30. 6. 2011, a 2. „prospektivní" část od tohoto data dále. Celá databáze je v anonymizované podobě vedena na Institutu biostatistiky a analýz Masarykovy univerzity v Brně (IBA MU). Očekáváme, že výsledky Czech TAVI Registry pomohou k zodpovězení výše nastolených klinických otázek.

Rationale

Aortic stenosis is the most common type of valve disease in the adults. Until recently its treatment was an exclusive domain of cardiac surgery. At the same time the aortic valve replacement (SAVR) was not indicated in about 1/3 of the patients [1] though the prognosis of conservatively treated patients is very unfavorable with one-year mortality rate of 50%. These facts were the main reasons for starting a new interventional era of the aortic valve disease therapy in 2002 [2]. From 2007 two new types of valves in stents have been commercially available – balloon expandable Edwards Sapien valve (Edwards Lifesciences, Inc., Irvine, California) and the selfexpanding CoreValve (Medtronic, Inc., Minnesota, USA) [3,4]. If the standard femoral approach is impossible to use there are several alternatives as the transapical, transsubclavian, transaortic or recently described transcarotid approaches. On the contrary to SAVR the native severely diseased aortic valve remains in place enabling the new valve to reach a stable position.

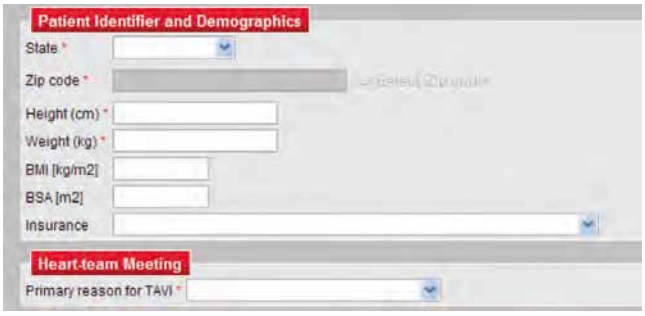

Fig. 1 – Patient identifier, demographics and heart-team decision.

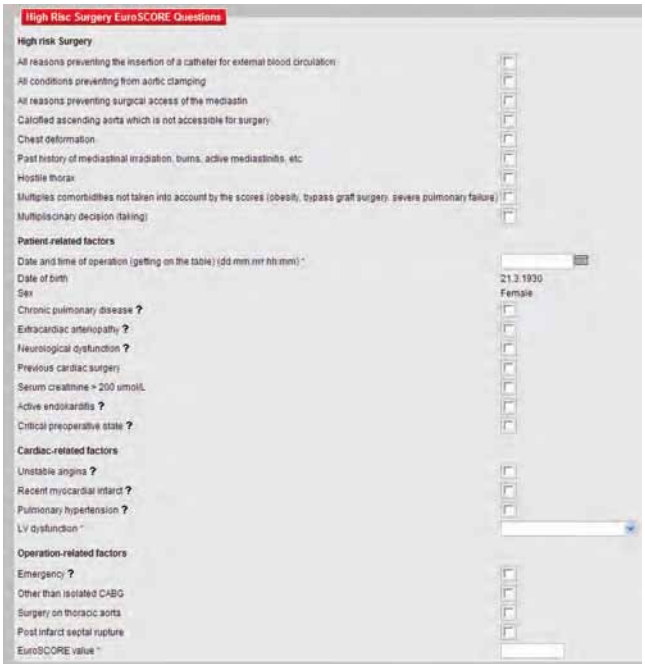

Fig. 2 – Calculation of EuroSCORE.

Fig. 3 – Medical history, CAD risk factors and the type of previous interventions.
CAD – coronary artery disease.

In the early phase the transcatheter aortic valve implantation (TAVI) was used just in patients with contraindication to SAVR or with high perioperative risk after surgery. In some countries the increased experience and good short- and middle-term results of TAVI resulted in broad application of TAVI nearly as equivalent to SAVR. Some problems have to be solved before general acceptance of such strategy: 1. what clinical impact will the relative high rate of paravalvular leaks have? and 2. what will be the function of the implanted valve in real long-term follow-up exceeding 5 years?

Besides the randomized trials comparing the TAVI vs. SAVR [5,6] and several registries [7–9] it is important to

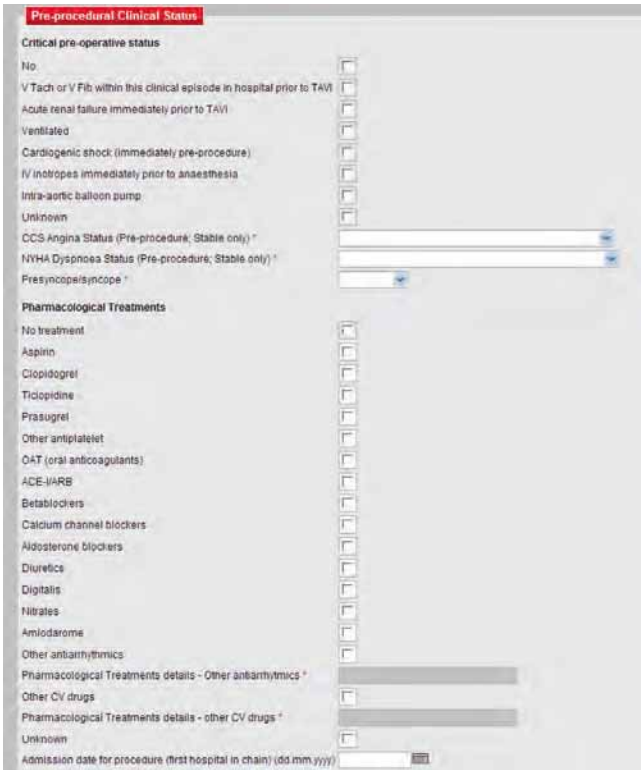

Fig. 4 – Pre-procedural clinical status.

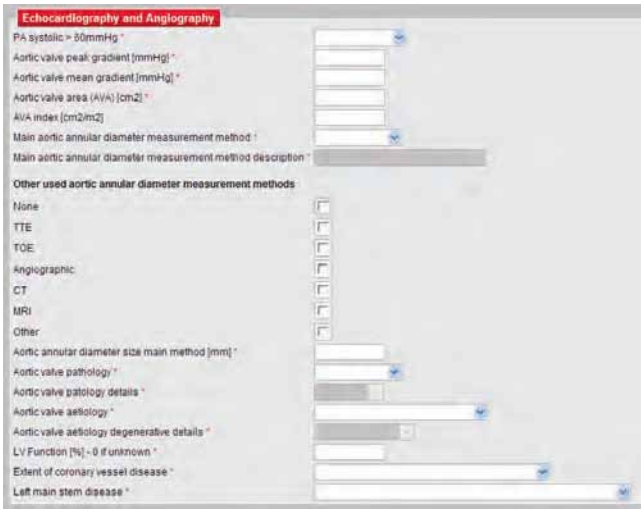

Fig. 5 – Echocardiographic and angiographic findings.

get also our own national data. The Czech TAVI Registry comprises the use of both currently available types of valves and the results can help to answer the above mentioned and clinically relevant questions.

TAVI program in the Czech Republic

In the Czech Republic the first TAVI was performed in Prague, IKEM in December 2008 [10]. During a short period of time the TAVI program was initiated also in other complex cardiovascular centers in Hradec Kralove [11], Brno [12], Prague – FN Kralovske Vinohrady and Trinec. Including the later starting centres (Usti n. Labem, Olomouc, Ceske Budejovice and other three centers in Prague – Nemocnice Na Homolce, FN Motol and VFN) there is a total of 11 centers providing the TAVI at present. All centers except one (FN Motol) are part of the Czech TAVI Registry that was developed with the support

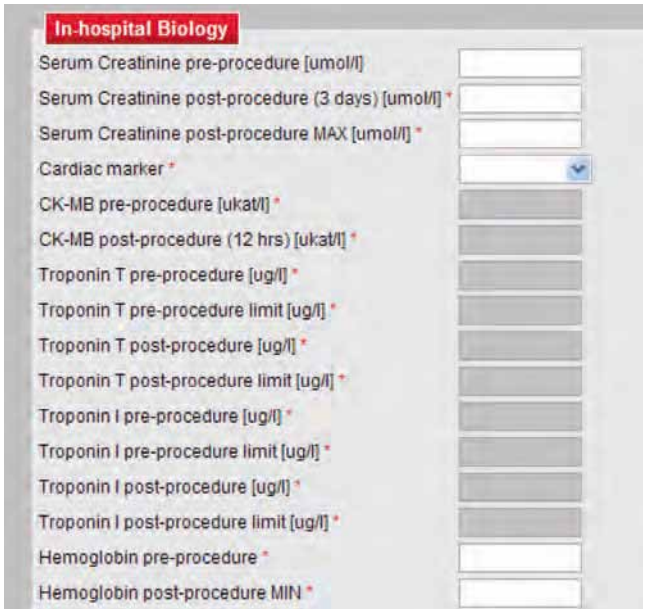

Fig. 6 – In-hospital biology before and after TAVI.
TAVI – transcatheter aortic valve implantation.

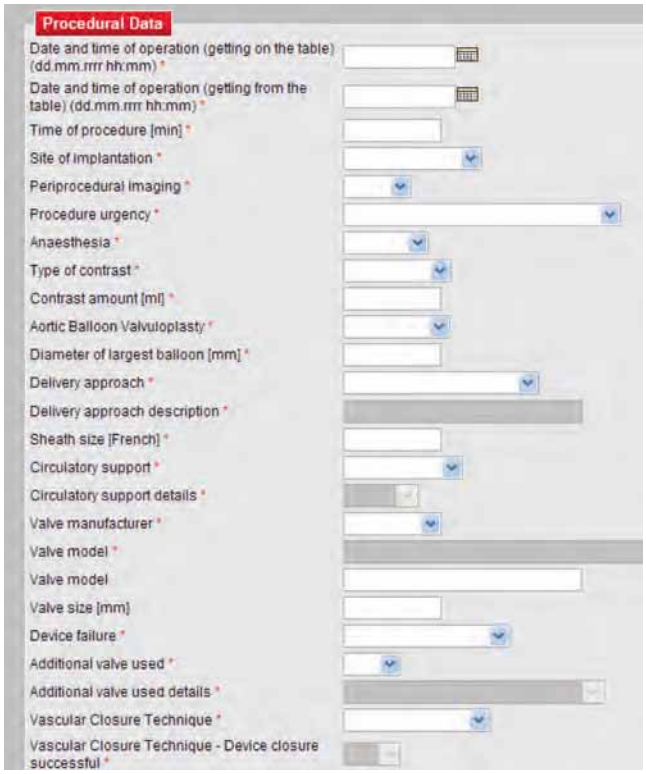

Fig. 7 – Procedural data.

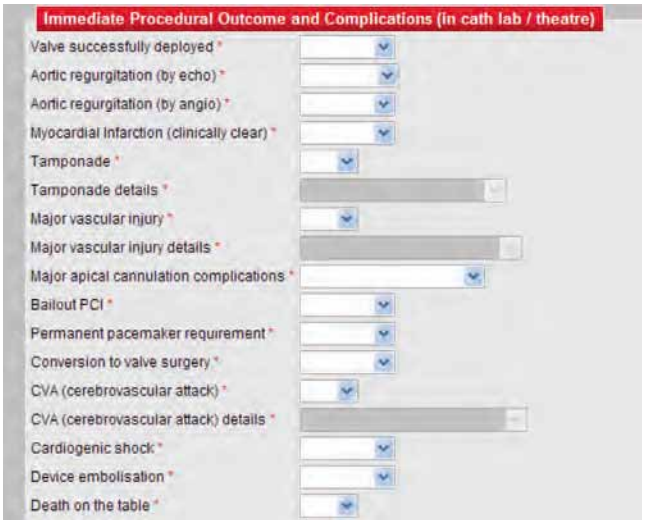

Fig. 8 – Immediate procedural outcome and complications.

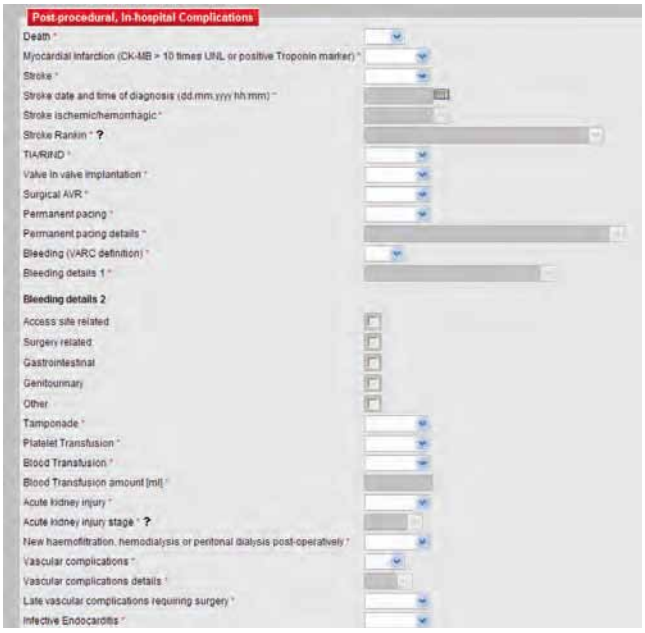

Fig. 9 – Post-procedural in-hospital complications.

of the Czech Society of Cardiology and started on September 1, 2010. The structure of the Registry was planned with the valuable help of Professor Carlo di Mario, the President of the European Association of PCI (EAPCI) at that time. In general and more theoretically there are two parts of the Registry: 1. "Retrospective" including all the TAVI procedures from the beginning of the TAVI program in the Czech Republic that was terminated on June 30, 2011 and 2. "Prospective" that has been following. Institute of Biostatistics and Analyses of Masaryk University takes care of the online and anonymized database. Since April 2012 the centres receive regularly benchmarks showing their own results in comparison with the mean data from the whole country. Dataset described in the paper enables a very good collaboration with the ongoing European TCVT (TransCutaneous Valve

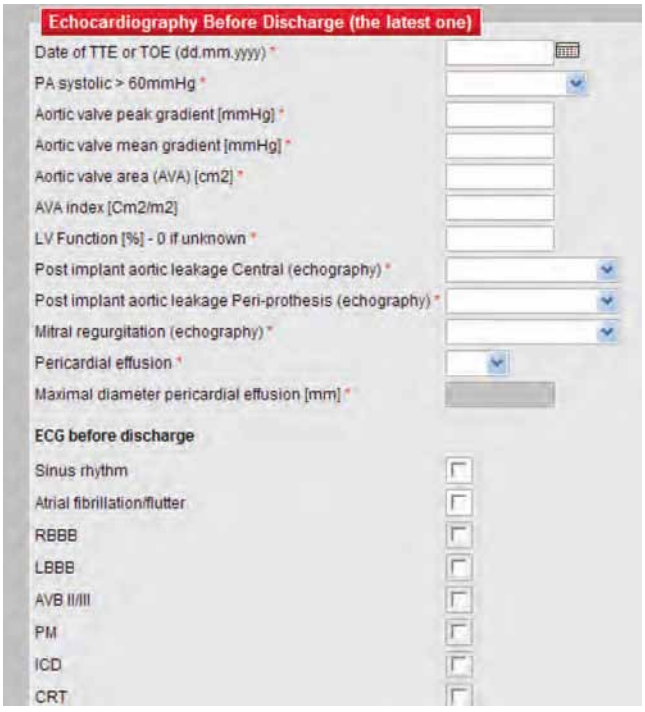

Fig. 10 – Echocardiographic findings before discharge.

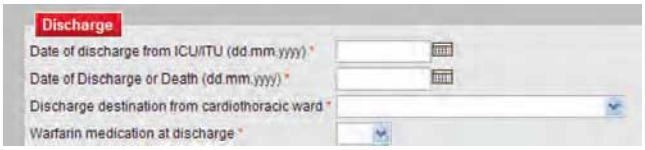

Fig. 11 – Dataset at discharge.

Therapy) Pilot Registry supported by the European Society of Cardiology. Just the Czech Republic and Poland represent the middle-east European countries in this important project that started in the beginning of 2012.

Czech TAVI Registry – dataset

The web-based Czech TAVI Registry has two main parts describing the hospital phase and follow-up of the patients at 1 month and yearly after the procedure.

1. Hospital phase
   a. Pre-procedural data (Fig. 1–6)
   b. Procedural data (Fig. 7, 8)
   c. Post-procedural data (Fig. 6, 9–11)
2. Follow-up (Fig. 12)

The total of 222 in-hospital parameters and 19 parameters during each follow-up are collected. Separate questionnaire has to be filled in if the patient dies. All the data are marked as Pending – Completed – Uncollectable.

General description of the Czech TAVI Registry can be found at www.registry.cz/index.php?pg=projekty&prid=60. Direct link to the database (http://tavi.registry.cz) is used by the investigators from participating centers.

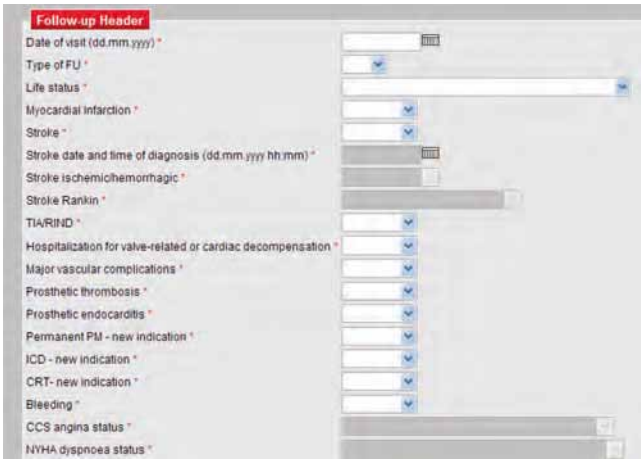

Fig. 12 – Follow-up evaluation.

Other national and international TAVI registries

There are several other national and international ongoing TAVI registries both in Europe and outside Europe, e.g. Belgian, Canadian, French, German, Italian, Israeli, SOURCE, Swiss, UK, WIN TAVI Registries, STS/ACC TVT Registry and already mentioned European TCVT Pilot Registry. The high number of different TAVI registries and ongoing big trials (PARTNER II, SURTAVI) may serve as a potent marker of the importance of TAVI. In relatively near future the optimal treatment strategy of patients with severe aortic stenoses might be changed and TAVI has the potential to do it.

Conclusion

Czech TAVI Registry is a nation-wide registry including more than 90% of all the Czech centers and about 95% of all the TAVI procedures performed in the Czech Republic. The first analyses with at least 1-year outcome of 250 patients will be completed in 2012.

Acknowledgements

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