

# Hubungan Antara Severitas Anatomi Aneurisma Aorta Abdominalis Dan Kesesuaian Indications For Use Endurant Medtronic Dengan Kesuksesan Implantasi Prosedur Endovascular Aneurysm Repair Di Indonesia Tahun 2013-2019 = Relationship Between Anatomical Severity of Abdominal Aortic Aneurysm and Suitability of Indications for Use Endurant Medtronic with the Success of Implantation Endovascular Aneurysm Repair Procedures in Indonesia 2013-2019

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## Abstrak

Latar belakang : Sejak munculnya EVAR pada 1990an, pengalaman dan teknologi mengenai stent graft semakin maju. Di RSCM pertama kali dilakukan pada tahun 2013. Menurut Ad Hoc Committee for Standarized Reporting Practices in Vascular Surgery of the Society for Vascular Surgery, keberhasilan teknis utama membutuhkan pengenalan sistem alat ini dengan baik. Sebelum melakukan tindakan EVAR, ahli bedah vaskular harus menilai severitas anatomi untuk disesuaikan dengan IFU dari Endurant Medtronic. Belum banyak penelitian yang menggambarkan hubungan antara kesesuaian teknis EVAR dengan IFU.

Metode : Penelitian ini bersifat deskriptif analitik dengan design cross-sectional pada pasien yang menjalani EVAR oleh ahli bedah vaskular di Indonesia pada tahun 2013-2019. Data ditabulasi untuk mengetahui adanya hubungan antara implantasi prosedur EVAR sesuai IFU dengan technical intraoperating complication (TIC) pada pasien AAA, dilakukan uji Chi-Square jika distribusi data normal atau Mann-Whitney test jika distribusi data tidak normal. Pengolahan data pada penelitian ini menggunakan program SPSS 20.0 untuk membantu perhitungan statistik.

Hasil : Didapatkan 103 data aneurisma aorta abdominalis yang menjalani EVAR dari tahun 2013-2019. Terdapat 99 pasien (96.1%) pria dan 4 pasien (3.9%) wanita dan sebanyak 8 pasien (7.8%) berusia dibawah 60 tahun serta 95 pasien (92.2%) berusia diatas 60 tahun. Berdasarkan klasifikasi aortic neck severity score didapatkan 49 pasien (47.6%) memiliki klasifikasi ringan, 47 pasien (45.6%) dengan klasifikasi sedang, dan 7 pasien (6.8%) dengan klasifikasi berat. Berdasarkan klasifikasi total aortic anatomy severity score didapatkan 61 pasien (59.2%) dengan klasifikasi ringan, 42 pasien (40.8%) dengan klasifikasi sedang, dan 0 pasien (0%) dengan klasifikasi berat. Sebanyak 86 pasien (83.5%) prosedur EVAR dilakukan sesuai dengan IFU dan 17 pasien (16.5%) tidak sesuai dengan IFU. Dari data technical intraprocedure complication (TIC) didapatkan 19 pasien (18.4%) mengalami TIC dan 84 pasien (81.6%) tidak mengalami TIC. Dari penelitian ini didapatkan sebanyak 13 pasien (76.5%) yang tidak mengalami TIC dilakukan tindakan EVAR tidak sesuai IFU dan sesuai dengan IFU sebanyak 71 orang (82.6%). Sedangkan, sebanyak 4 pasien (23.5%) yang mengalami TIC dilakukan tindakan EVAR yang tidak sesuai IFU dan sebanyak 15 pasien (17,4%) yang mengalami TIC dilakukan tindakan EVAR sesuai dengan IFU. Pada data ini dihasilkan data OR (95% interval kepercayaan) sebesar 1.848 (0.385-8.864) dengan nilai  $p=0.556$

Kesimpulan : Dari penelitian ini didapatkan hasil diameter leher proksimal, aortic neck severity score dan klasifikasi total aortic anatomy severity secara independen memiliki hubungan yang signifikan dengan kejadian TIC pada pasien AAA di Indonesia tahun 2013-2019 dengan nilai  $p<0.05$  dan secara umum skoring

severitas anatomi memiliki pengaruh terhadap kejadian TIC setelah tindakan EVAR dan variasi anatomi menjadi pertimbangan untuk dilakukannya tindakan EVAR. Sedangkan faktor lainnya seperti panjang leher proksimal, angulasi aortic, kalsifikasi, trombus, usia, jenis kelamin, dan IFU secara independen tidak memiliki hubungan yang signifikan dengan kejadian TIC.

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**Background.** Since EVAR in the 1990s, the experience and technology of stent-graft has advanced. At the RSCM, it was first carried out in 2013. According to the Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery of the Society for Vascular Surgery, major technical success requires a good introduction to this system of tools. Before performing an EVAR procedure, vascular surgeons must assess the severity of the anatomy to match the IFU of Endurant Medtronics. Not many studies have described the relationship between EVAR's technical suitability and IFU.

**Method.** This study is analytic with cross-sectional design in patients undergoing EVAR by vascular surgeons in Indonesia in 2013-2019. Data were tabulated to determine the relationship between implantation of the EVAR procedure according to IFU and technical intraoperative complication (TIC) in AAA patients, Chi-square test was performed if the data distribution was normal or the Mann -Whitney test if the data distribution was abnormal. Data processing in this study uses the SPSS 20.0 program to help statistical calculations.

**Results.** 103 data obtained from abdominal aortic aneurysms undergoing EVAR from 2013-2019. There were 99 patients (96.1%) male and 4 patients (3.9%) female and as many as 8 patients (7.8%) aged under 60 years and 95 patients (92.2%) aged over 60 years. Based on the classification of aortic neck severity score, 49 patients (47.6%) had a mild classification, 47 patients (45.6%) with a moderate classification, and 7 patients (6.8%) with a severe classification. Based on the total aortic anatomy severity score classification, there were 61 patients (59.2%) with mild classification, 42 patients (40.8%) with moderate classification, and 0 patients (0%) with severe classification. A total of 86 patients (83.5%) EVAR procedures were performed following IFU and 17 patients (16.5%) did not comply with IFU. From technical intraoperative complication (TIC) data, 19 patients (18.4%) experienced TIC and 84 patients (81.6%) did not experience TIC. From this study, there were 13 patients (76.5%) who did not experience TIC. EVAR measures were not performed according to IFU and according to IFU, there were 71 people (82.6%). Meanwhile, as many as 4 patients (23.5%) who experienced TIC were performed EVAR actions that were not IFU compliant and as many as 15 patients (17.4%) who experienced TIC were performed EVAR measures according to IFU. In this data generated OR data (95% confidence interval) of 1,848 (0.385-8,864) with a value of  $p = 0.556$

**Conclusion.** From this study the results obtained proximal neck diameter, aortic neck severity score and total classification of aortic anatomic severity independently have a significant relationship with the incidence of TIC in AAA patients in Indonesia in 2013-2019 with a p-value  $<0.05$  and in general the scoring of anatomical severity has an influence the occurrence of TIC after the EVAR procedure and anatomic variations are considered for the EVAR procedure. While other factors such as proximal neck length, aortic angulation, calcification, thrombus, age, sex, and IFU independently did not have a significant relationship with the incidence of TIC.