

Hubungan pemakaian stent berdasarkan Instructions for Use (IFU) pada Endovascular Aortic Repair (EVAR) terhadap Angka Kejadian Endoleak = Association Between Instruction for Use (IFU) Accordance in Endovascular Aortic Repair (EVAR) and Post-EVAR Endoleak

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Abstrak

Latar Belakang: Endovascular repair of abdominal aortic aneurysms (EVAR) menggunakan stent graft merupakan terapi utama pada pasien dengan aneurisma aorta abdominal. Aplikasi klinis EVAR dihadapkan dengan tingginya variasi anatomik aneurisma yang menyebabkan ketidaksesuaian ukuran stent yang dapat menyebabkan komplikasi berupa endoleak. Pembuatan instructions for use (IFU) merupakan upaya standardisasi dari produsen stent sehingga dapat sesuai dengan kondisi anatomik pasien dan menghindari komplikasi. Belum adanya penelitian mengenai kesesuaian IFU pada EVAR dan keluaran operasinya khususnya endoleak pasca-EVAR. Penelitian ini ditujukan untuk melihat hubungan kesesuaian IFU pada EVAR dengan kejadian endoleak pasca-EVAR.

Metode: Studi dilakukan secara kohort retrospektif yang menilai hubungan kesesuaian IFU pada EVAR dengan kejadian endoleak pasca-EVAR. Penelitian akan dilakukan dari bulan Desember 2018-Februari 2019 di Rumah Sakit dr. Cipto Mangunkusumo (RSCM). Pengambilan subjek dilakukan dengan pengambilan subjek total.

Hasil: Pada pengambilan subjek didapatkan 39 subjek yang menjalani prosedur EVAR. Pada penelitian ini didapatkan 27 subjek (69.2%) menjalani EVAR sesuai dengan IFU dan 12 subjek (30.8%) tidak sesuai dengan IFU. Pada penelitian ini didapatkan 3 subjek penelitian (7.7%) mengalami endoleak pasca-EVAR. Pada analisis data, ditunjukkan bahwa kesesuaian IFU dalam menjalani EVAR tidak menunjukkan hubungan yang bermakna dengan kejadian endoleak pasca-EVAR ($p=0.539$). Pada penelitian ini didapatkan bahwa seluruh pasien yang mengalami endoleak pasca-EVAR berasal dari kelompok yang menjalankan IFU yang sesuai. Analisis data panjang, sudut, dan diameter leher juga tidak menunjukkan hubungan yang bermakna dengan kejadian endoleak pasca-EVAR.

Kesimpulan: Tidak terdapat adanya hubungan antara kesesuaian IFU dalam menjalani EVAR dengan kejadian endoleak pasca-EVAR.

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Background: Endovascular repair of abdominal aortic aneurysms (EVAR) with stent-graft is the main treatment for patients with abdominal aortic aneurysm. Clinical application of EVAR is faced with the wide anatomic variety of aneurysm that could lead to incompatibility of stent size that could cause complications like endoleak. Instruction of use (IFU) is a standardization effort from the producer of the stent so that it would be more suitable for the patients anatomical condition thus avoiding the complications. Up until now, there has not been a research that studied the use of IFU on EVAR and its post-surgical outcome, especially post-EVAR endoleak. The objective of this study is to see the association between IFU accordance in EVAR with post-EVAR endoleak.

Method: The study was conducted by cohort-retrospective which assesses the association between IFU accordance in EVAR with post-EVAR endoleak. This study was done from December 2018 to February

2019 at vascular surgery out-patient clinic in Cipto Mangunkusumo Hospital. Total sampling was conducted to obtain subjects by collecting all patients treated by EVAR.

Results: There were 39 subjects selected in this study. We found 27 subjects (69.2%) underwent EVAR appropriately according to IFU and 12 subjects (30.8%) that did not. Three of the subjects (7.7%) had post-EVAR endoleak. In the data analysis, IFU accordance in EVAR did not have a significant association with post-EVAR endoleak incidence ($p=0.539$). This study also found that every single subject with post-EVAR endoleak was from the IFU appropriate EVAR group. Data analysis on neck length, angle, and diameter also did not show any significant association with post-EVAR endoleak incidence ($p>0.05$).

Conclusion: There is no association between IFU accordance in EVAR with post-EVAR endoleak. Another study with larger sample size is needed to show association between IFU accordance with post-EVAR endoleak more accurately.