

G3-CAP – Registry

Grade 3 CoronAry P Perforation multicenter registry

Incidence, predictors, management and outcomes

BACKGROUND

Grade III coronary perforation or coronary rupture is an extremely rare but well recognized complication of percutaneous coronary intervention (PCI) The incidence of grades I to III coronary perforation ranges from 0.1% to 3.0%. (1,2).A previous meta-analysis focused on this topic including 965 cases among all three types of perforation according to the Ellis classification. Grade III coronary perforation is certainly the most serious form of perforation and it is associated with the highest mortality rates (7%-44% of cases) very high rate of cardiac tamponade (almost half of cases) or emergent CABG (20%-40%) (3 –6). Some retrospective registries specifically reported about the grade III subgroup alone although with a low overall numerosity. The largest registry up to now was published by Al-Lamee, Colombo A et al (7) including 56 patients (**table 1**)

Table 1: overview of published studies

Author	Overall	Ellis 1	Ellis 2	Ellis 3
Kiernan	68	30	25	13
Jacob	35	NA	NA	NA
Panagiota	5	1	1	3
Shimony	57	7	30	20
Shirakabe	12	3	2	7
Javaid	72	14	33	25
Ramana	25	6	10	9
Stankovic	84	0	56	28
Witzke	39	8	15	16
Fasseas	95	17	58	20
Eggbrecht	19	NA	7	10
Gunning	52	NA	NA	NA
Dippel	36	0	19	16
Gruberg	84	NA	NA	NA
Ellis	62	13	31	18
Ajluni	35	NA	NA	NA
Al-Lamee	56	0	0	56
Liu Y	64	NA	NA	NA
Hendry	44	0	8	36
Copeland	21	7	9	3
Total (20 studies)	965	106	304	280

The improvement of interventional techniques in the last years provided new devices and techniques (including coils, glues, microcatheters) helping the operator to solve this hazardous complication. Conversely the best strategy according to the underlying mechanism of perforation is not well defined (i.e. for instance distal guidewires perforation versus proximal coronary rupture subsequent to balloon dilatation)

METHODS

The study will be multicenter involving high volumes of coronary intervention.(see below “Invited centers”)

Aim of the study is to report the incidence, predictors, treatment, and long-term outcomes of all patients with grade III coronary perforation as a complication of PCI in the real-world setting.

Successful of treatment of grade III perforation, Major Adverse Cardiac Event (MACE) and its single composite will be recorded. (see below “study definitions”).

Additionally, a pre-specified analysis according to perforation / rupture will be provided in order to explore differences in acute management of perforation.

All cases of grade III coronary perforation, as defined by the Ellis et al. will be included. Baseline date, procedural characteristics, devices related to perforation, immediate management, short term and long term outcomes will be recorded in a dedicated database published online on our website (<http://www.cardiogroup.org/protocols/index.php?cat=perforation>)

STUDY DEFINITIONS.

Grade III coronary perforation or coronary rupture: extravasation of blood through a frank perforation (≥ 1 mm) or into an anatomic cavity chamber on coronary angiography (Ellis et al. criteria)⁽⁸⁾.

Successful treatment of grade III perforation: absence of any angiographic evidence of contrast extravasation or clinical or echocardiographic signs of cardiac tamponade.

Stent restenosis: $\geq 50\%$ diameter stenosis by quantitative coronary angiography within a previously stented segment.

Target lesion revascularization (TLR) any repeat revascularization for a stenosis within the stent or within the 5-mm borders adjacent to the stent.

Target vessel revascularization (TVR) need for any repeat revascularization on a treated vessel.

Major adverse cardiac event (MACE) combination of all cause mortality, MI, TLR, TVR, and need for CABG.

Stent thrombosis (ST) was defined according to the Academic Research Consortium (9) definitions and cumulative ST as a combination of all episodes of ST during follow-up.

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