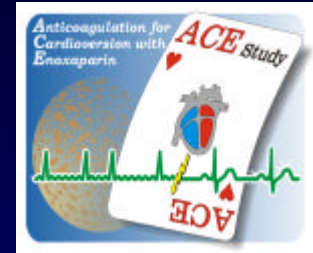


Anticoagulation for Cardioversion using Enoxaparin

Stellbrink C, Nixdorff U, Hofmann T, Kühle K, Grewe R,
Hanrath P, Lehmacher W, Schmidt-Lucke JA
- on behalf of the ACE Investigators -

Potential Advantages of LMWH in AF Cardioversion



Conventional Anticoagulation:

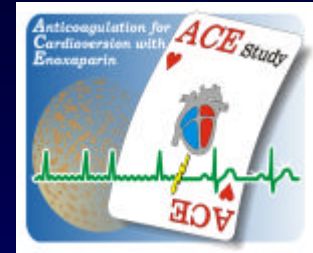
- ...is frequently underused due to fear of bleeding complications¹.
- ...requires frequent anticoagulation monitoring.

Low Molecular Weight Heparins:

- ...allow ambulatory therapy initiation (s.c. administration).
- ...do not require routine anticoagulation checks².
- ...are safe and effective in non-randomized studies of cardioversion^{5,6}.

¹Lip et al., *Br Heart J* 1994; ²Hirsh et al. *Chest* 2001; ³Cohen et al. *NEJM* 1997; ⁴ASSENT-3 *Lancet* 2001; ⁵Harenberg *Semin Thromb Hemost* 1997; ⁶Rojer et al. *Eur Heart J* 2000

Aim of the Study



Evaluate in a prospective randomized, open-label multicenter trial the efficacy and safety of

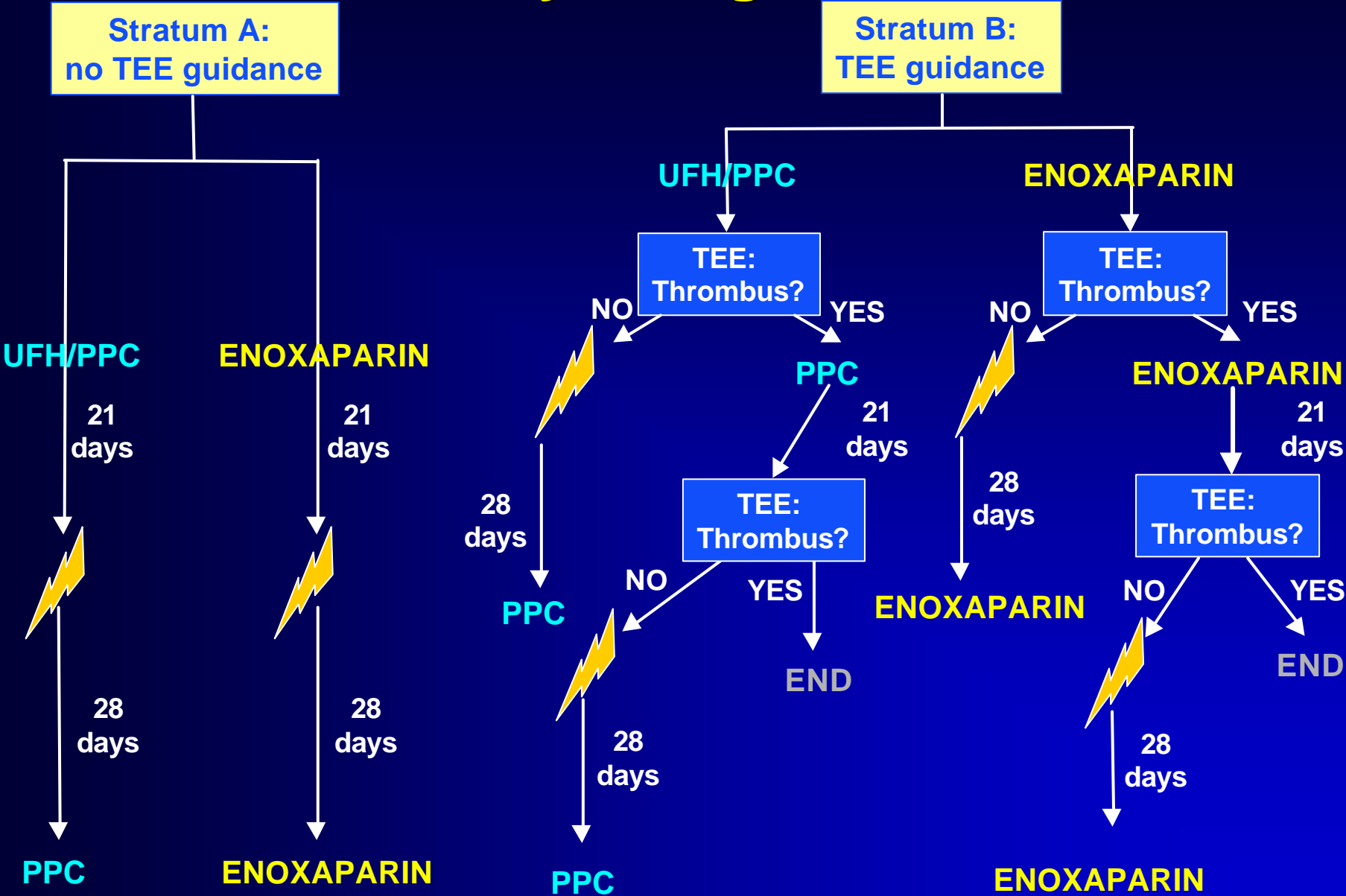
– s.c. enoxaparin

vs.

– i.v. UFH and phenprocoumon (PPC)

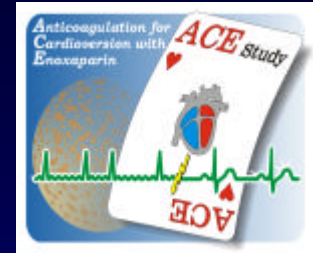
in cardioversion of **non-valvular** AF

Study Design



 =CARDIOVERSION; AF=ATRIAL FIBRILLATION; TEE=TRANSESOPHAGEAL ECHOCARDIOGRAPHY; UFH=UNFRACTIONATED HEPARIN; PPC=PHENPROCOUMON

Study Endpoints*



Composite primary endpoint:

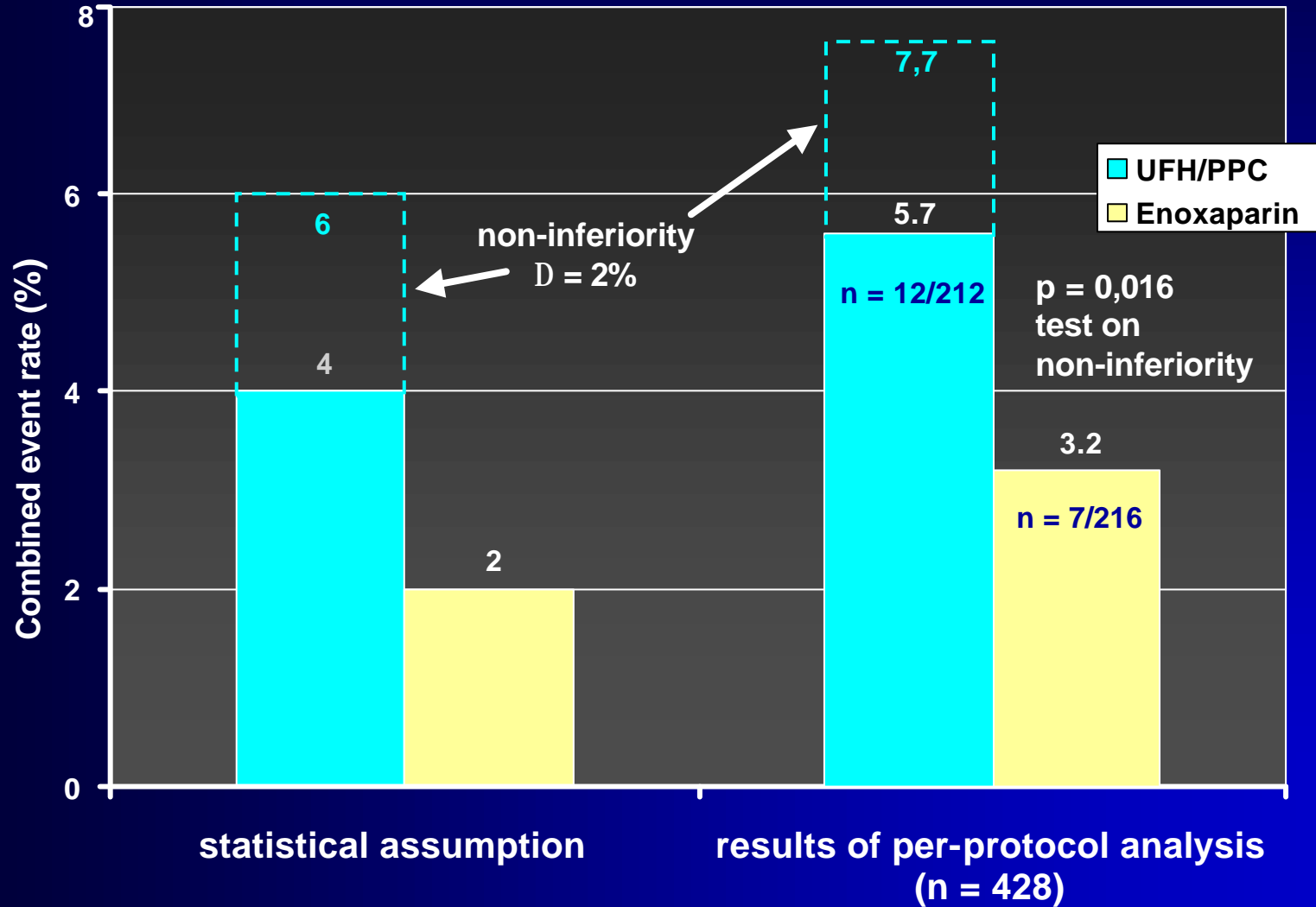
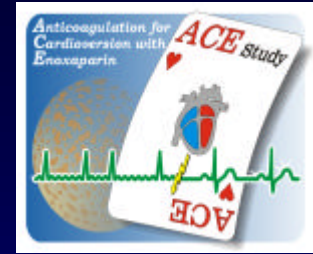
- Cerebral-ischemic neurological events,
- Systemic thromboembolism,
- Major bleeding complications and
- Death from any cause

Secondary endpoints:

Successful cardioversions, patients in sinus rhythm at study end, other bleeding complications (except major bleedings), injection hematoma ≥ 5 cm

***All serious adverse events adjudicated by independent CEC
Blinded review of all primary endpoint events by independent ERC**

Results: Primary Endpoint

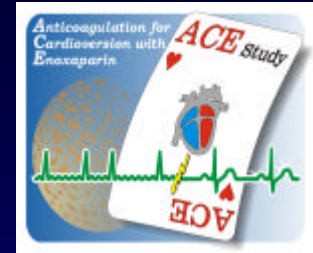


Primary Endpoint Events (ITT, n=496)



Events	Enoxaparin (n=248)	UFH/PPC (n=248)
Composite Endpoint n (%)	7 (2.8%)	12 (4.8%)
• Embolic events n (%)	2 (0.8%)	4 (1.6%)
• Major hemorrhage n (%)	2 (0.8%)	6 (2.4%)
• Deaths n (%)	3 (1.2%)	5 (2.0%)

Conclusions



Enoxaparin

- ...is **non-inferior** to UFH/phenprocoumon for the prevention of bleeding and embolism in cardioversion of non-valvular AF.
 - ...offers
 - ease of s.c. administration
 - reduced need for anticoagulation monitoring
- ➔ ...may be the preferred drug for this purpose.**