

Valutazione di parametri procedurali e risultati in acuto durante ablazione di fibrillazione atriale utilizzando cateteri con sensore di forza tradizionale e con nuovo struttura

Per l'ablazione della fibrillazione atriale (FA), sono stati introdotti negli ultimi anni cateteri dotati di forza di contatto per ottimizzare l'efficacia di ablazione ed aumentare la sicurezza. Lo scopo di questo studio è quello di effettuare un'analisi relativa alla prestazione del nuovo catetere **Tacticath SE (St. Jude Medical/Abbott Medical)** rispetto al tradizionale **Tacticath Quartz (St.Jude Medical)**

Ablazione fibrillazione atriale

Cateteri con sensore di contatto

- Ablazione classe I per pazienti con f.a. sintomatica dopo tentativo di trattamento farmacologico
- Isolamento delle vene polmonari +/- integrazione con altri target

Ma

- Efficacia ancora imperfetta, con una percentuale di inefficacia attestabile sul 20% dei pazienti
- Incidenza di procedure RE-DO da 30% a 50%.
- In occasione di SEF di controllo riscontro di riconnessione vene polmonari

The relationship between contact force and clinical outcome during radiofrequency catheter ablation of atrial fibrillation in the TOCCATA study

BACKGROUND The clinical efficacy of catheter ablation of paroxysmal atrial fibrillation (AF) remains limited by difficulty in achieving durable pulmonary vein isolation (PVI). Suboptimal catheter tip-to-tissue contact force (CF) during lesion delivery is believed to reduce clinical efficacy.

RESULTS Acute PVI was achieved in 100% of the veins. Thirty-five percent (351 of 1017) of the applications were placed with an average CF of <10 g (low CF). All patients treated with an average CF of <10 g (5 of 5 patients) experienced recurrences, whereas 80% of the patients treated with an average CF of >20 g (8 of 10 patients) were free from AF recurrence at 12 months. The analysis of the average force-time integral showed that 75% of the patients treated with <500 gs were recurrent whereas only 31% of the patients treated with >1000 gs had recurrences at 12 months.

CONCLUSIONS The CF during catheter ablation for AF correlates with clinical outcome. Arrhythmia control is best achieved when ablation lesions are placed with an average CF of >20 g, and clinical failure is universally noted with an average CF of <10 g.

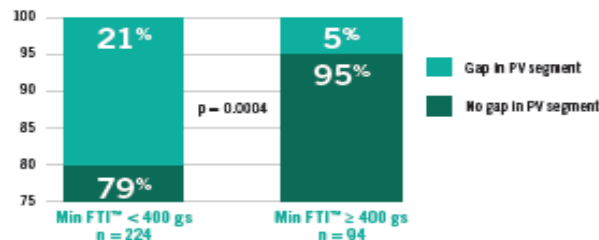
EFFICAS I ed EFFICAS II

EFFICAS I

- The EFFICAS I trial evaluated the association between CF and the existence of gaps during pulmonary vein (PV) isolation and at a three-month invasive follow-up.³
- Acute isolation success rate was 100% for all PVs (n = 46).
- Without contact force information, a large proportion of the 3,152 ablations were made with low contact force and low force-time integral (FTI[™]).
- One or more PV segment isolation gaps (reconnections) were found in 65% of 40 patients evaluated at the three-month follow-up procedure.
- When comparing segments with no gap vs. gap segments, a significant difference was noted in the *minimum* CF (8.1 g vs. 3.6 g, respectively, p < 0.0001).
- The *minimum* FTI value was also correlated to PV gap reconnection at three months post-procedure (n = 40).³
- Minimum FTI was found to be the best statistical predictor of PV isolation at three months.

Figure 4: EFFICAS I: PVI Success Rates at Three Months by Minimum FTI³

Min CF and Min FTI[™] are the best predictors for isolation – CF Blinded

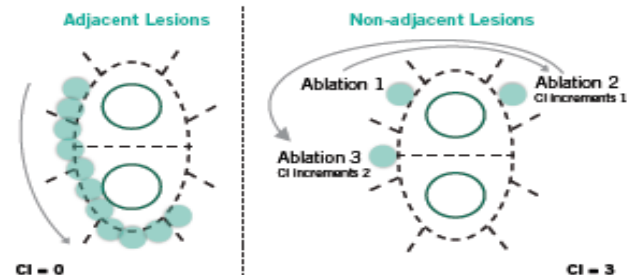


- Ablations with minimum FTI ≥ 400 gs, at 24.4 W average power, were associated with significantly higher PVI success (p = 0.0004) (Figure 4).
- Creating fewer lesions, efficiently, was associated with higher probability of PVI success.
- The total number of ablations per segment was inversely correlated to isolation (median six for isolated segments vs. nine for segments with gaps, p < 0.0001).
- Once an ablation with FTI < 400 gs was made, the risk of gap increased. Thus, EFFICAS I data suggested that successful transmural lesions achieved in one shot do not require subsequent corrections.³

EFFICAS II

- The EFFICAS II study validated that contiguous lesions created following the CF recommendations identified in EFFICAS I (Min CF > 10 g and Min FTI > 400 gs) resulted in improved ablation outcomes.⁴
- Continuity of each PVI lesion line was quantified using a Continuity Index[™] (CI) (previously referred to as "Jump Index", JI)⁹ that calculates how often the catheter is moved for ablation to noncontiguous locations (Figure 5).⁴
- Each gap between non-adjacent lesion points increases the CI for the lesion line by one. A low CI (CI < 6) is associated with good continuity and a high CI (CI ≥ 6) with poor continuity.
- In EFFICAS II, creating contiguous lesions with a low Continuity Index (CI < 6) significantly increased the number of PVs isolated when compared to PVs isolated with a high Continuity Index (CI ≥ 6) (98% vs. 62%, p < 0.001).

Figure 5: EFFICAS II: Continuity Index⁴



Cateteri con sensore di contatto

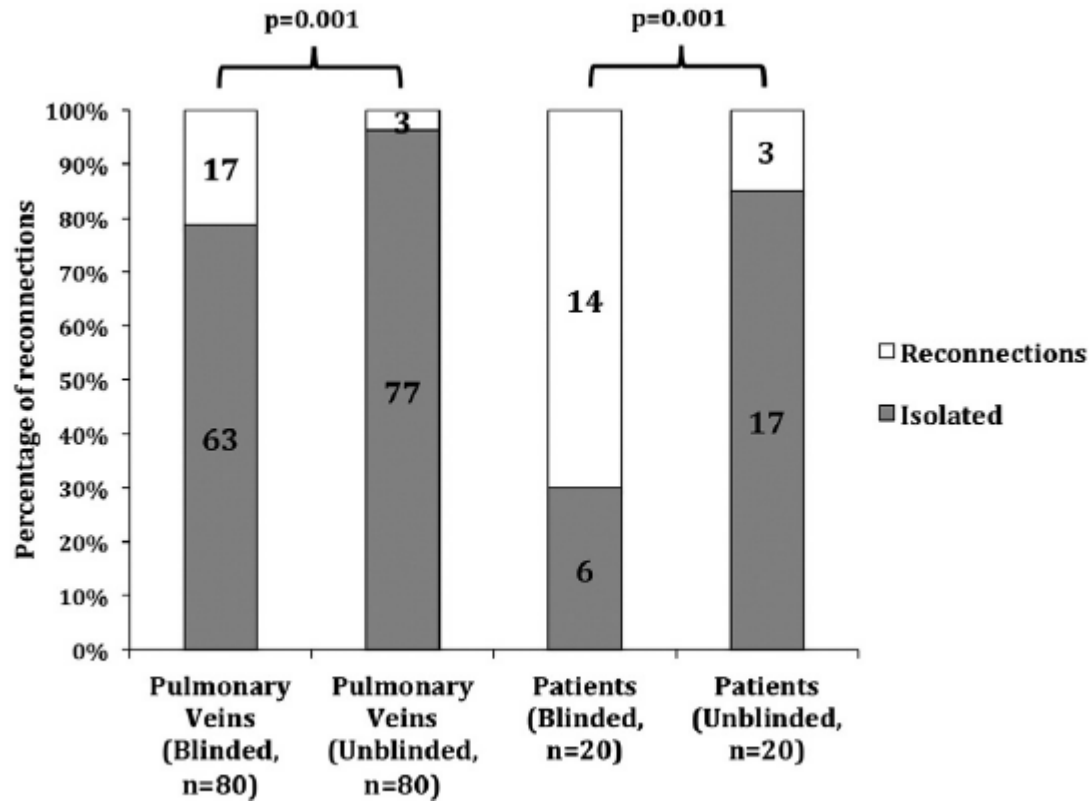
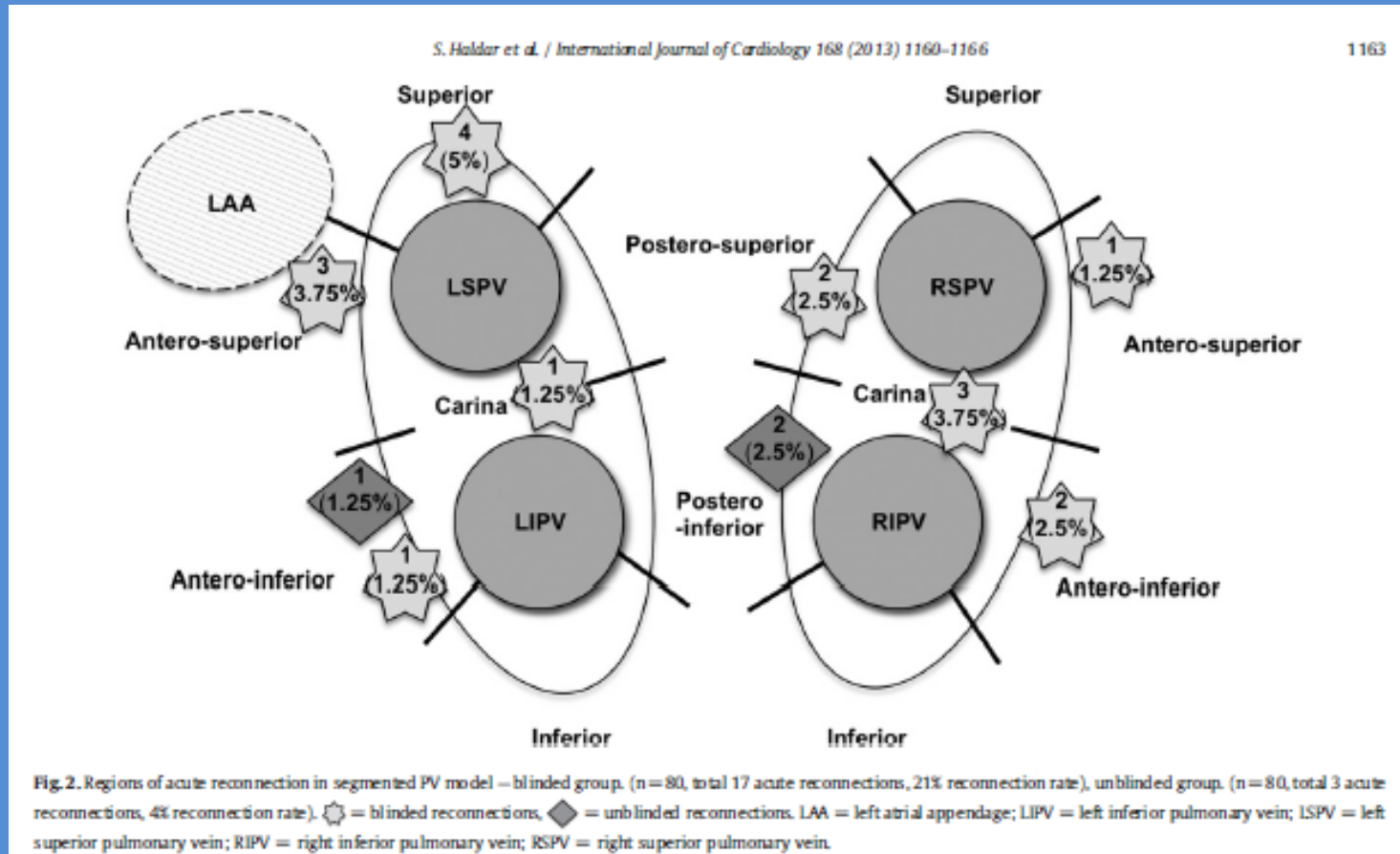


Fig. 1. Number of acute PV reconnections at PV and patient level

Zone con contatto “difficoltoso”



EFFICAS I

- Associazione tra CF e presenza di gap isolamento vene dopo 3 mesi
- Operatori non consapevoli della CF applicata
- Isolamento inizialmente efficace nel 100% delle vene
- Gap riscontrato del 65% dei pazienti
- Analisi retrospettiva evidenza che zone con gap rispetto a non-gap avevano avuto CF minima 3,6 VS 8,3g ($p= 0,0001$)

TOCCASTAR

valutazione procedure e operatori

CF >10g per >90% delle applicazioni
successo clinico 76% VS 58%

36 operatori:

10 con CF ottimale in tutti i pazienti;

13 con CF ottimale in nessun paziente

Flexability – Tachticath – Tacticath SE



FlexAbility

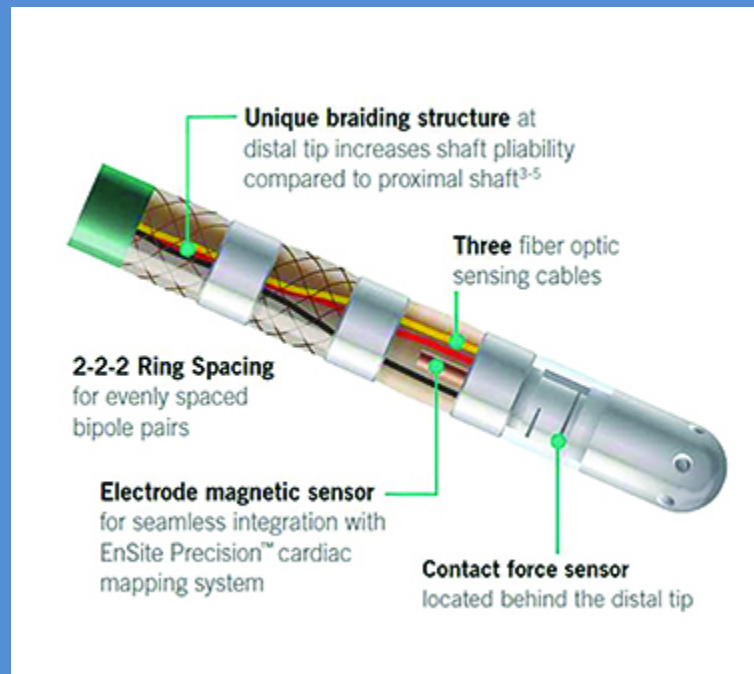


TactiCath



TactiCath SE

Tachicath SE



Introduttore Agilis



Parametri di ablazione

Tab.2 Dati di forza e parametri di lesione		Avg Contact Force (g)	Min Contact Force (g)	Max Contact Force (g)	FTI (gs)	LSI
1	QUARTZ+AGILIS	17,1	5,1	42,3	162,1	5,1
2	QUARTZ+AGILIS	15,4	4,0	40,7	167,5	5,1
3	QUARTZ+AGILIS	15,4	6,8	27,8	64,3	4,4
4	QUARTZ+AGILIS	12,1	4,7	29,5	133,7	4,5
5	SE	8,7	2,2	22,5	99,5	3,9
6	SE	8,8	2,8	20,4	55,1	3,4
7	SE	7,0	1,4	20,9	78,5	3,3
8	SE	21,5	12,7	37,1	210,5	5,2
TACTICATH QUARTZ + AGILIS valori medi		15,0	5,1	35,1	131,9	4,8
TACTICATH SE valori medi		11,5	4,8	25,2	110,9	3,9

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Valutazione di parametri procedurali

Tab.1 Dati Pocedurali	# RF	# Lesion	# transitions	RF time (min)	Avg RF Power (W)	Tempo procedura (min)	Tempo procedura dev std (min)
TACTICATH QUARTZ + AGILIS	23	156	113	35	35	121,3	10,8
TACTICATH SE	21	135	85	27	31	102,5	20,1

Considerazioni

Virtualmente ogni elettrofisiologo che effettua ablazioni della fibrillazione atriale ha l'impressione che la CF sui cateteri sia un enorme passo in avanti