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First time data release: Paclitaxel-coated balloon in below-the-knee lesions: 6-months results from the Ranger BTK single center study

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Disclosure

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I have the following potential conflicts of interest to report:

☒ Consulting Boston Scientific

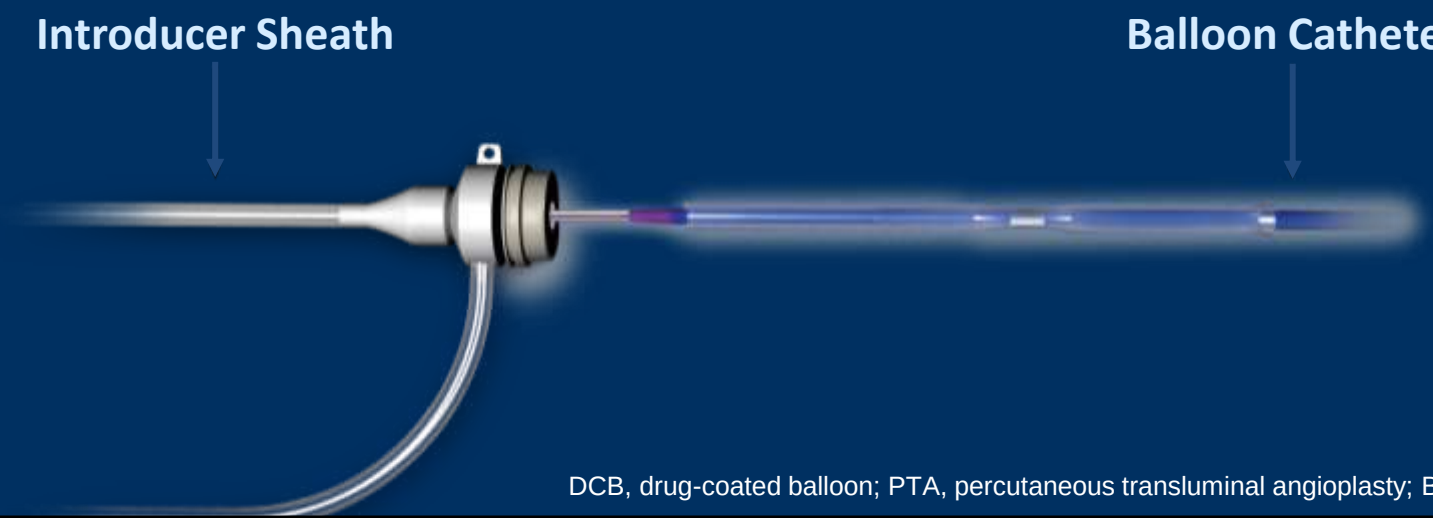
RANGER BTK Study Overview

Principal Investigator	**Prof Marc Sapoval, Phd, MD**
Study Sponsor	Assistance Publique Hôpitaux de Paris
Objective	To prove the superior performance of the Ranger™ paclitaxel-coated PTA balloon catheter (Boston Scientific) for angioplasty for below the knee artery lesions when compared to non-coated balloons at six months post-procedure
Study Design	Prospective, single centre, “all-comer”, non-randomized. Follow up through 1 years.
Subjects	30 patients with below the knee artery lesions (Rutherford 4-6, any lesion length)
Investigational Center	Hôpital Européen George Pompidou,
Endpoints	Primary efficacy: primary patency rate at 6 M FU safety: composite of all death and major amputation at 6 M FU. Secondary: late lumen loss at 6 M FU freedom from clinically driven TLR in the amputation free surviving patients at 6 M FU amputation Free Survival at 6 M FU Wound healing at 6 M FU Death at 6 M FU

ClinicalTrials.gov NCT02856230.

Ranger™ Paclitaxel-Coated PTA Balloon Catheter

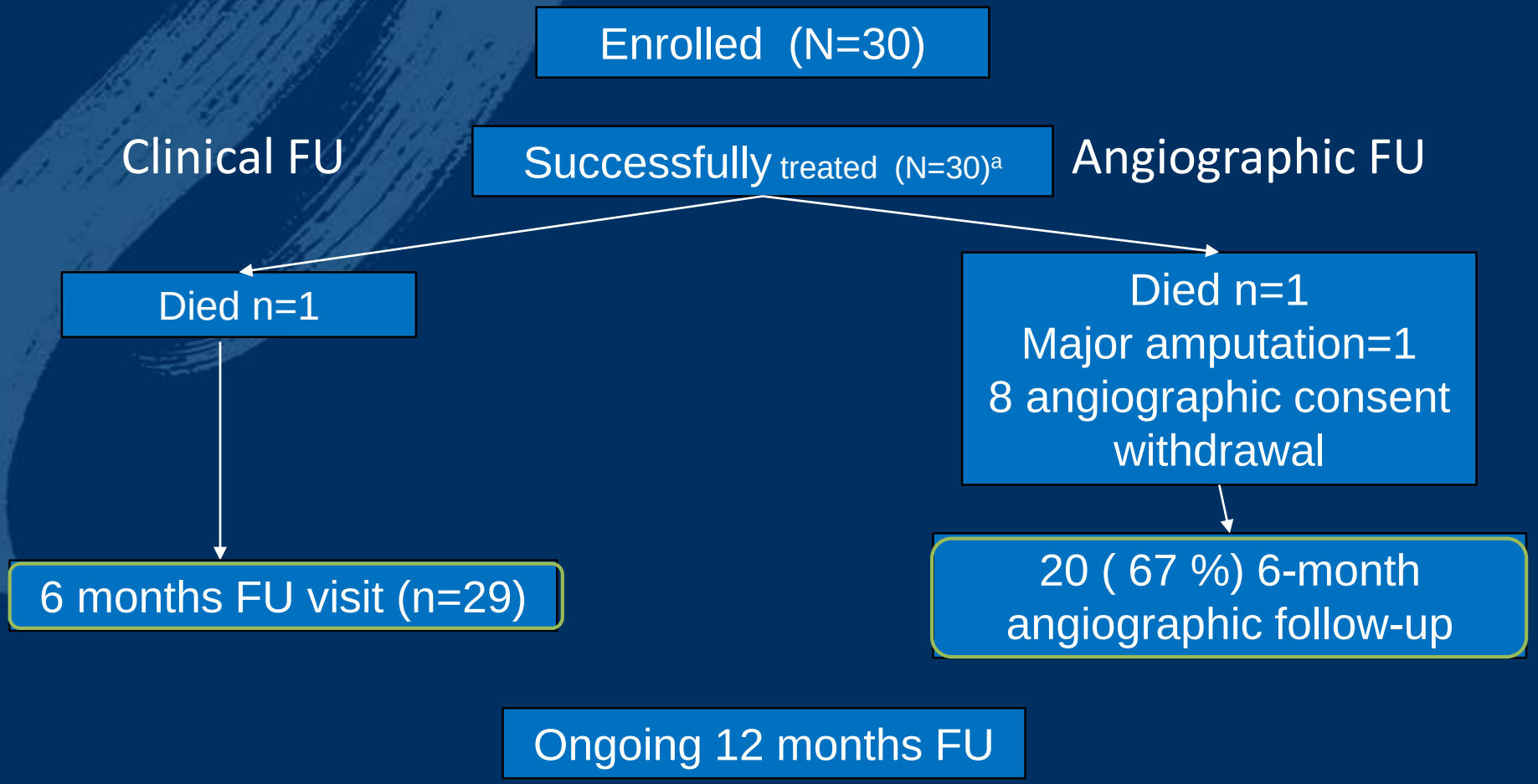
- Sterling™ PTA 0.014” balloon platform
- TransPax™ coating technology
- Paclitaxel: 2 µg/mm^2 dose density
- Sizes available for the RANGER BTK study:
  - 2-4 mm diameter; 40-150 mm length



DCB, drug-coated balloon; PTA, percutaneous transluminal angioplasty; BTK, below the knee

Patient Enrollment & Follow-up

- 30 consecutive patients between 11-2016 and 11-2017



[a]Enrollment occurred after successful intraluminal guidewire crossing of the target lesion

Patient Characteristics

	Ranger DCB (n=30)
Age, y	68.8±12.7
Men	80% (24/30)
Diabetes	63,3% (19/30)
Hypertension	80% (24/30)
Hyperlipidemia	70% (21/30)
Smoke	73% (22/30)
Previous smoker	53% (16/30)
Current smoker	6% (6/30)
Renal failure	40%(12/30)
Dialysis	17%(5/30)
Cardiac disease	77%(23/30)
Cerebrovascular disease	3%(1/30)
Rutherford Category	
4	3%(1/30)
5	70% (21/30)
6	27% (8/30)

Wound and lesions (baseline)

Ranger BTK had an “all-comer” setting

Wounds

	Ranger DCB (n=30)
Target Limb	
Left	53% (16/30)
Right	47% (14/30)
Baseline wound area (mm^2)	35.8±48.4

Lesions

	Ranger DCB (n=30)
Lesion lenght (mm)	113.1±94.3
Occlusion length (mm)	83.5±63.8
Target lesion CTO	60%(18/30)
Target lesion calcification degree	
Grade 0-2	37%(11/30)
Grade 3-4	63%(19/30)

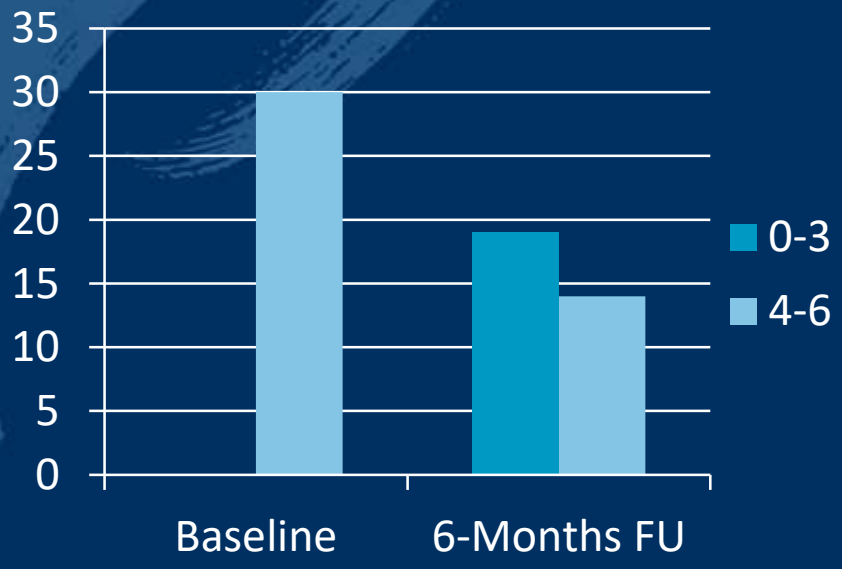
Endpoints

Efficacy endpoints:

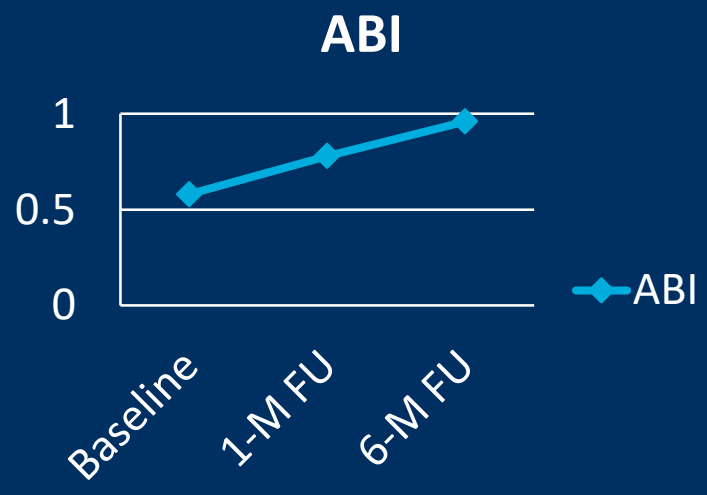
Primary patency rate at 6 M FU: 57,1% (N=20/30)

Late lumen loss at 6 M FU: 0,99±0,66

Freedom from clinically driven TLR at 6-M FU: 93,3%



Rutherford score improved p<0,0001



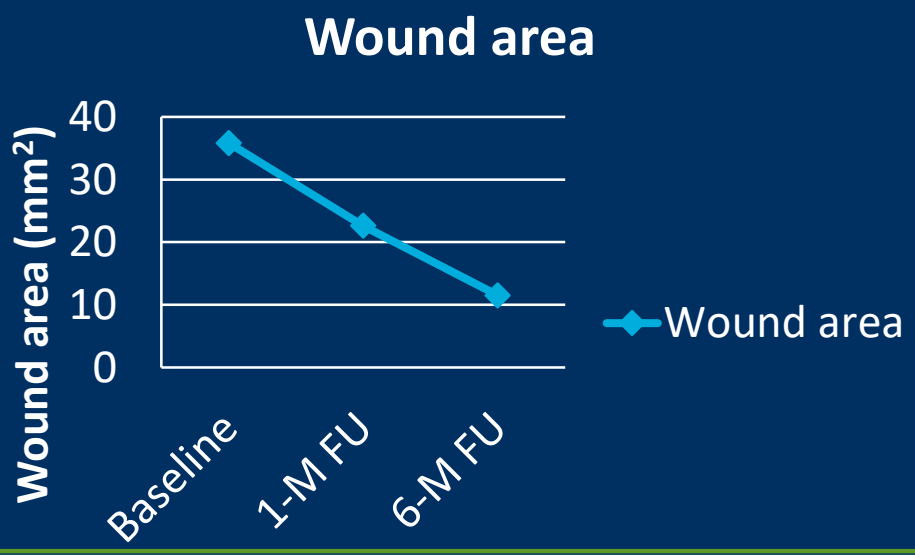
ABI index improved p=0,001

Endpoints

Safety endpoints:

Primary safety endpoint at 6M FU: 2/30 (6,6%)

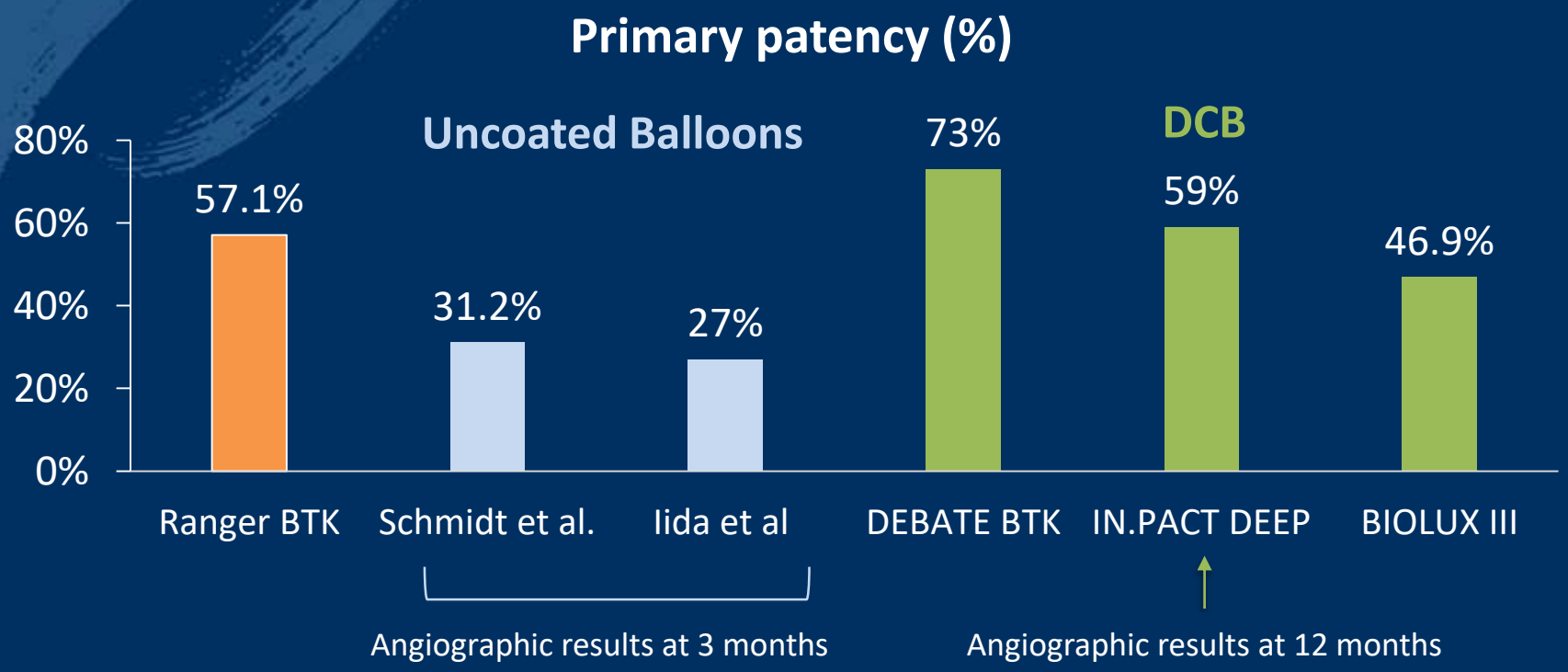
Amputation rate at 6 M FU: 1/30 (3,3%)
Wound healing at 6 M FU: 56,7%
Death at 6 M FU: 1/30 (3,3%) → cancer related death



Significant reduction of wound area p=0,0002

RANGER BTK Outcomes in “all-comer” setting

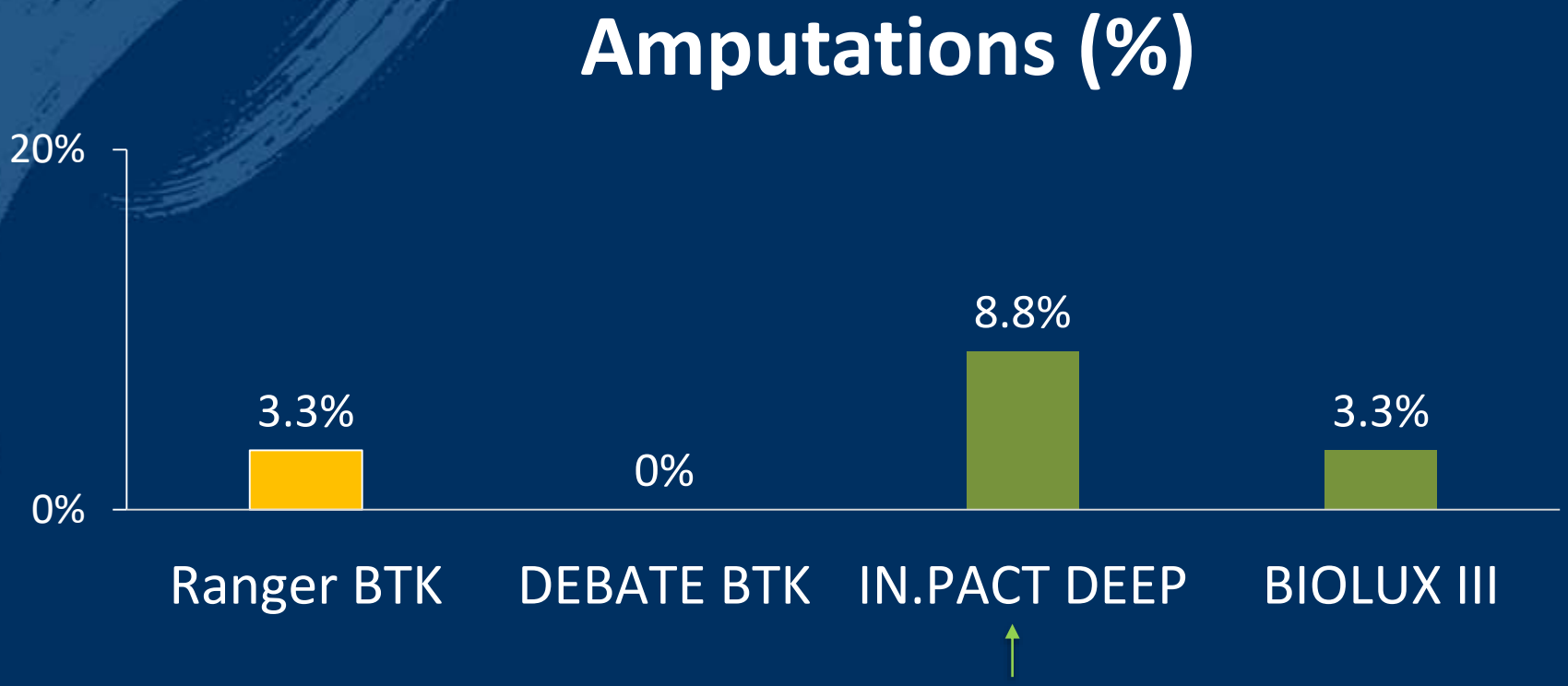
- Primary patency at 6-M FU 57,1%
- LLL 0,99±0,6 at 6 months angiographic results
- Freedom from TLR 93,3%



This investigator-sponsored study is supported by grant funding from Boston Scientific.
Boston Scientific is not responsible for the collection, analysis or reporting of these studies which remain the sole responsibility of the investigators.

Amputation at 6 m

- Only 1 major amputation 3 months after procedure (peri-procedural acute occlusion)



Conclusions

- The only acute occlusion was probably related to suboptimal peri-procedural anticoagulation
- Ranger BTK is safe in BTK intervention
- Effective inhibition of restenosis and good patency and clinical outcomes were observed for CLI patients treated with the Ranger DCB
- Limitations:
  - Small sample sizes
  - high rate of angiography consent withdrawal (bias) (26,7%)


KEEP
CALM
AND
LOVE
DRUGS

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