

Intergroup Exemestane Study: Results from the Quality of Life (QoL) Sub-protocol at 24 months

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on behalf of the IES Trialists**

Method

- **Sample:**

582 consenting patients recruited to QoL study
556 completed baseline questionnaires (pre randomisation)

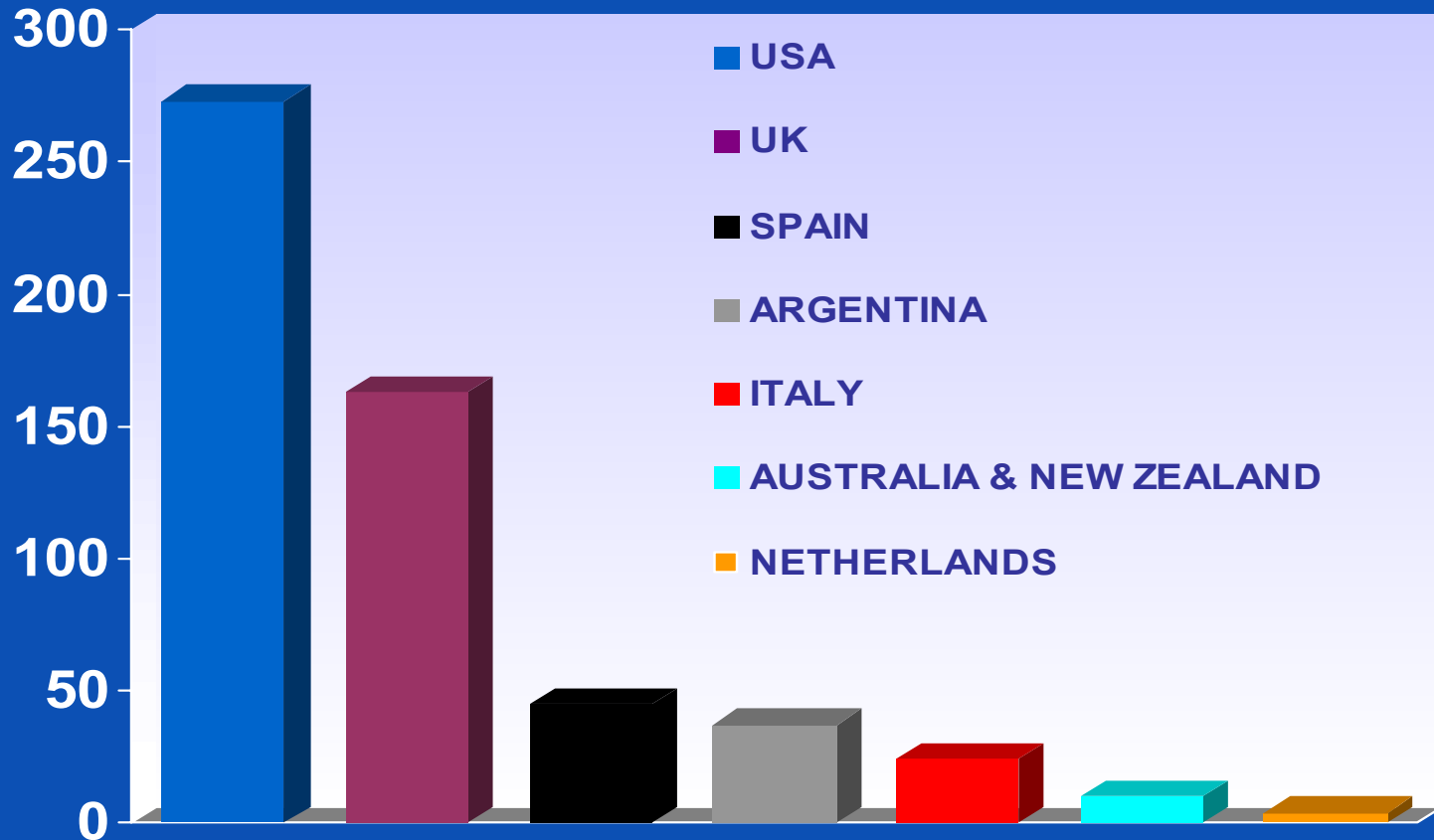
- **Assessments:**

- 3, 6, 12 months
- 6 monthly until 36 months
- yearly until 60 months
- 1 month post-recurrence

- **Results:**

from 24 months follow-up

Participating countries (N=8) & patients (N=556) in QoL sub-protocol



Baseline characteristics

No significant differences between treatment group in terms of:-

age

tumour size

nodal status

ER or PgR status

histological grade

surgery

primary localization

prior use of HRT

histological type

chemotherapy

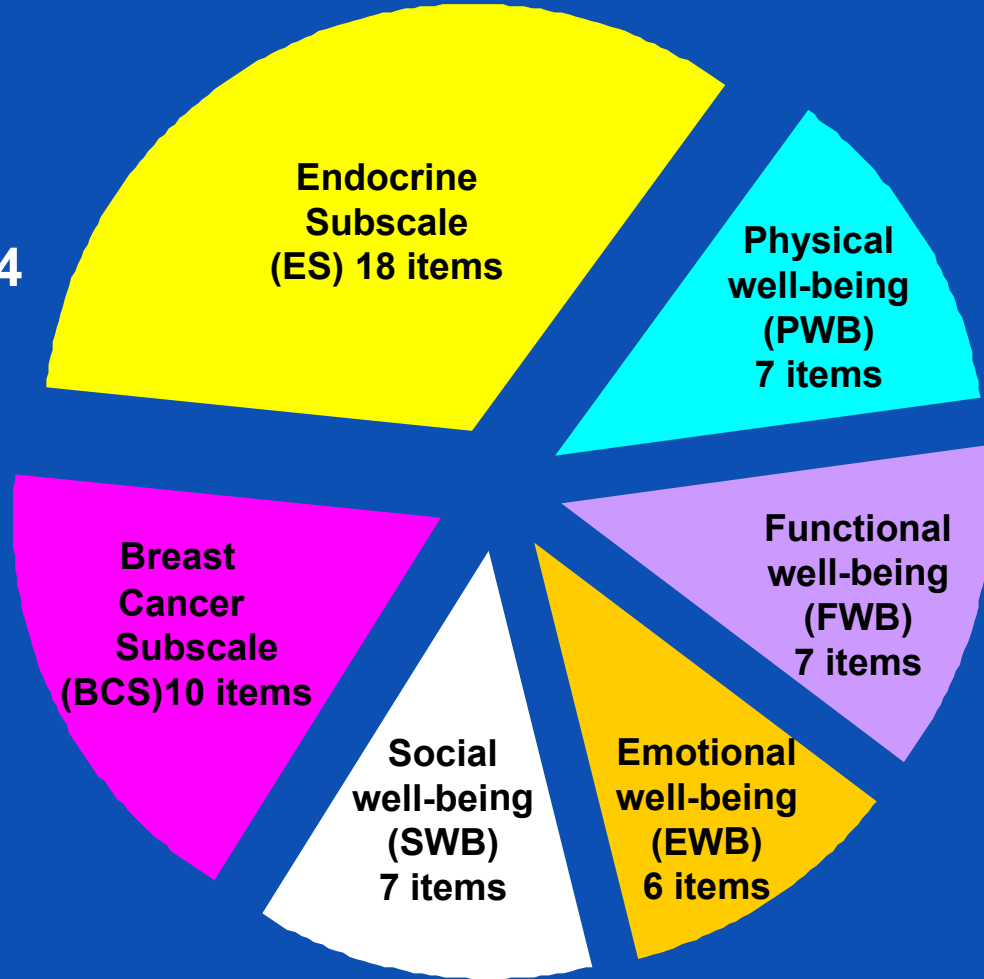
radiotherapy

country

FACT- B + ES subscale

Items scored on 5
point scale from 0 – 4

High score = good
QoL



(Fallowfield et al 1999)

Endocrine subscale items

hot flushes

cold sweats

night sweats

vaginal discharge

vaginal itching / irritation

vaginal bleeding or
spotting

vaginal dryness

dyspareunia

loss of interest in sex

weight gain

light-headed / dizzy

vomiting

diarrhoea

headaches

bloated feeling

breast sensitivity /

tenderness

mood swings

irritability

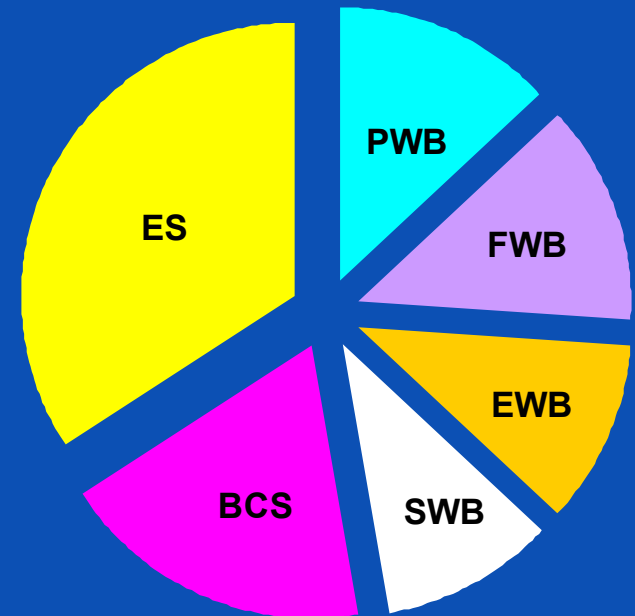
Endpoints

- **Primary endpoint**

- Trial Outcome Index (TOI)
PWB, FWB + BCS

- **Secondary endpoints**

- Total FACT B + ES scores
- Individual endocrine symptoms dichotomised into **severe** (very much/quite a bit) versus **not severe** (somewhat/ a little/ not at all)



Patient attrition in QoL sub-study over 2 years

Reason	E n= 281	T n= 275
recurrence/ death	3	18
adverse event	15	14
other /consent withdrawn	14	9
Total withdrawn patients	32	41

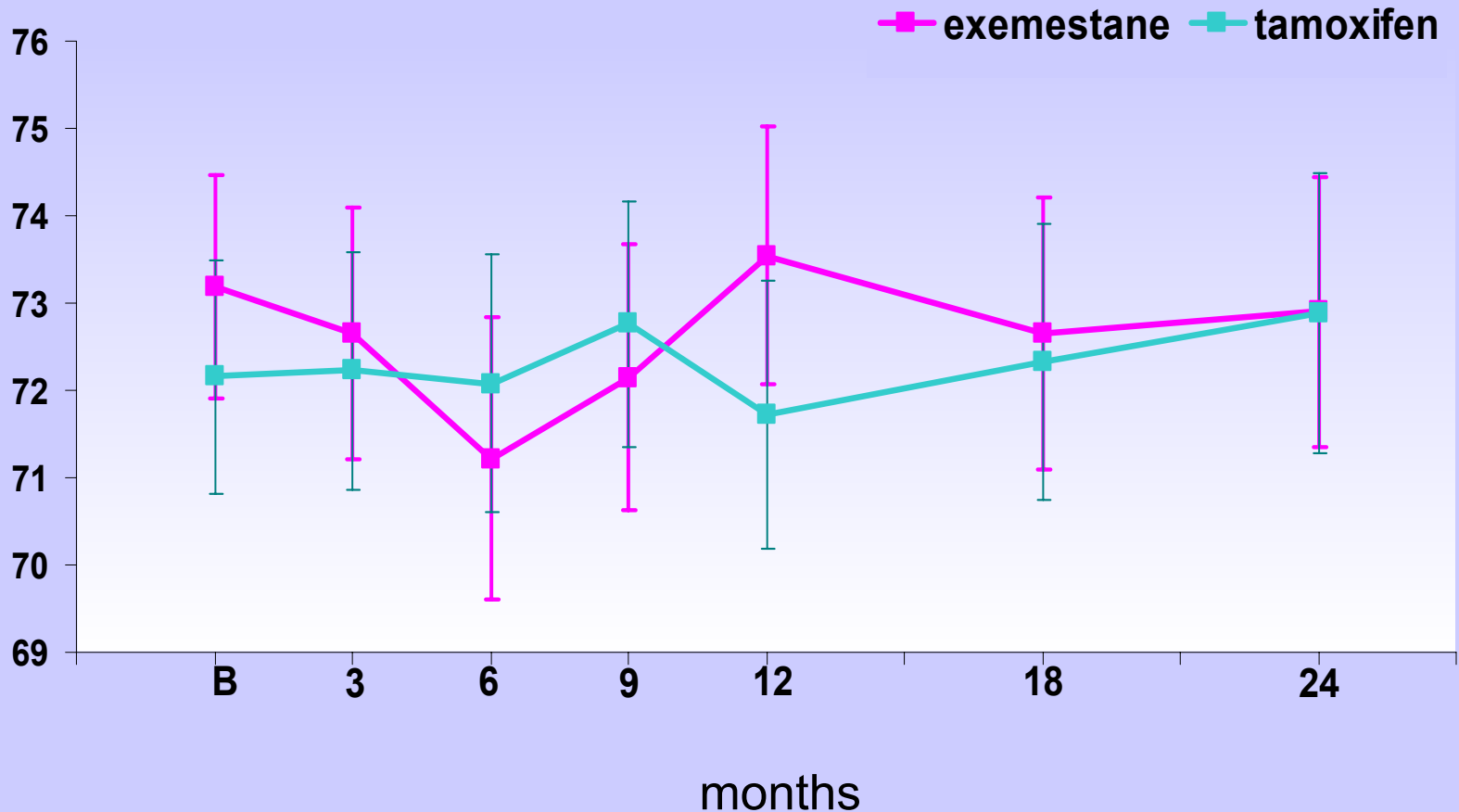
Questionnaire completion over 2 years

Reason for missingness	E	T
patient attrition	136	134
administrative error	60	63
patient choice	1	6
reason unknown	50	31
Total missing for any reason	247	234

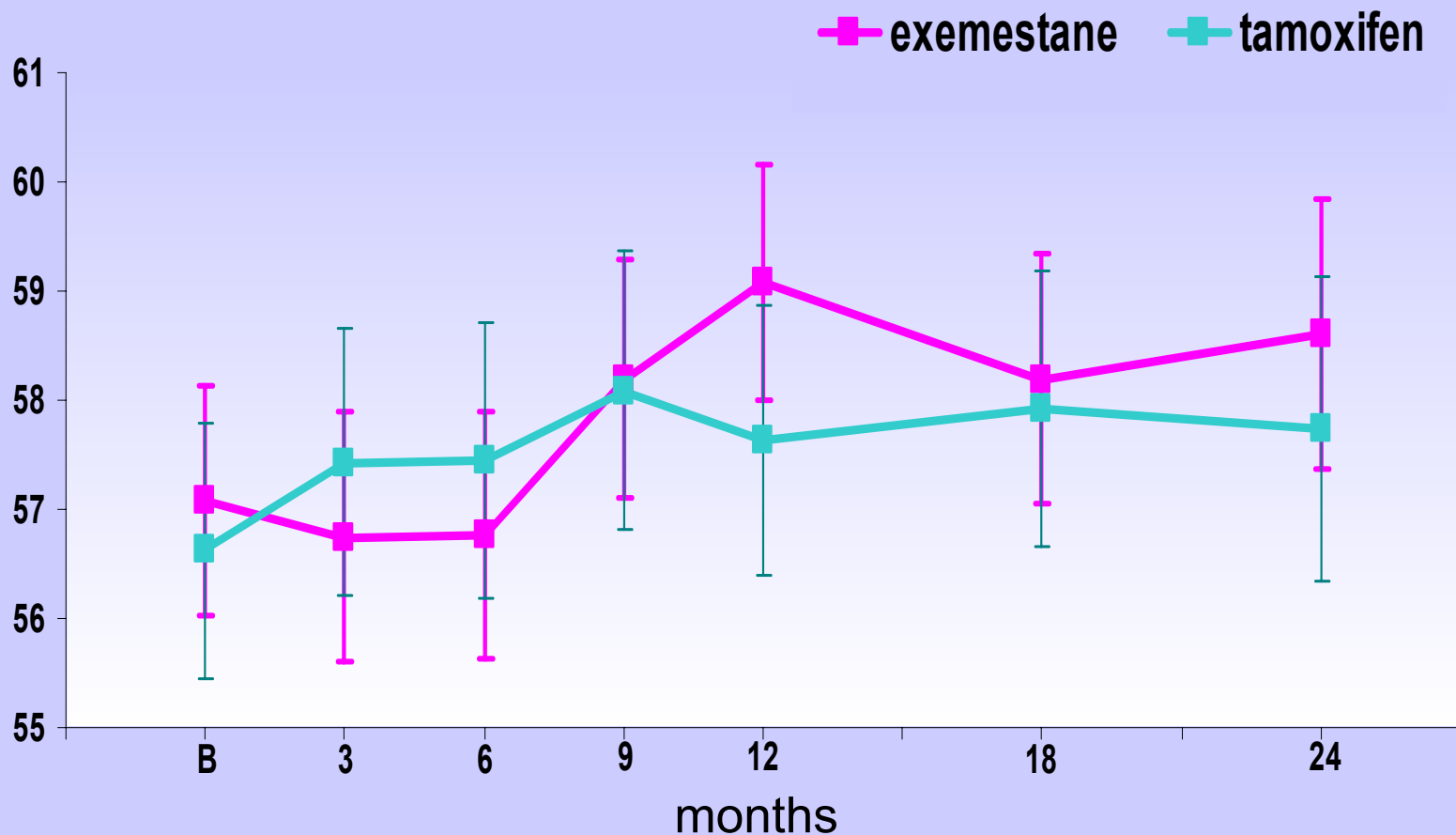
**3411/3892 (87.6%) questionnaires returned
and available for analysis**

TOI mean scores + 95% C.I.s

(5 point change clinically meaningful)

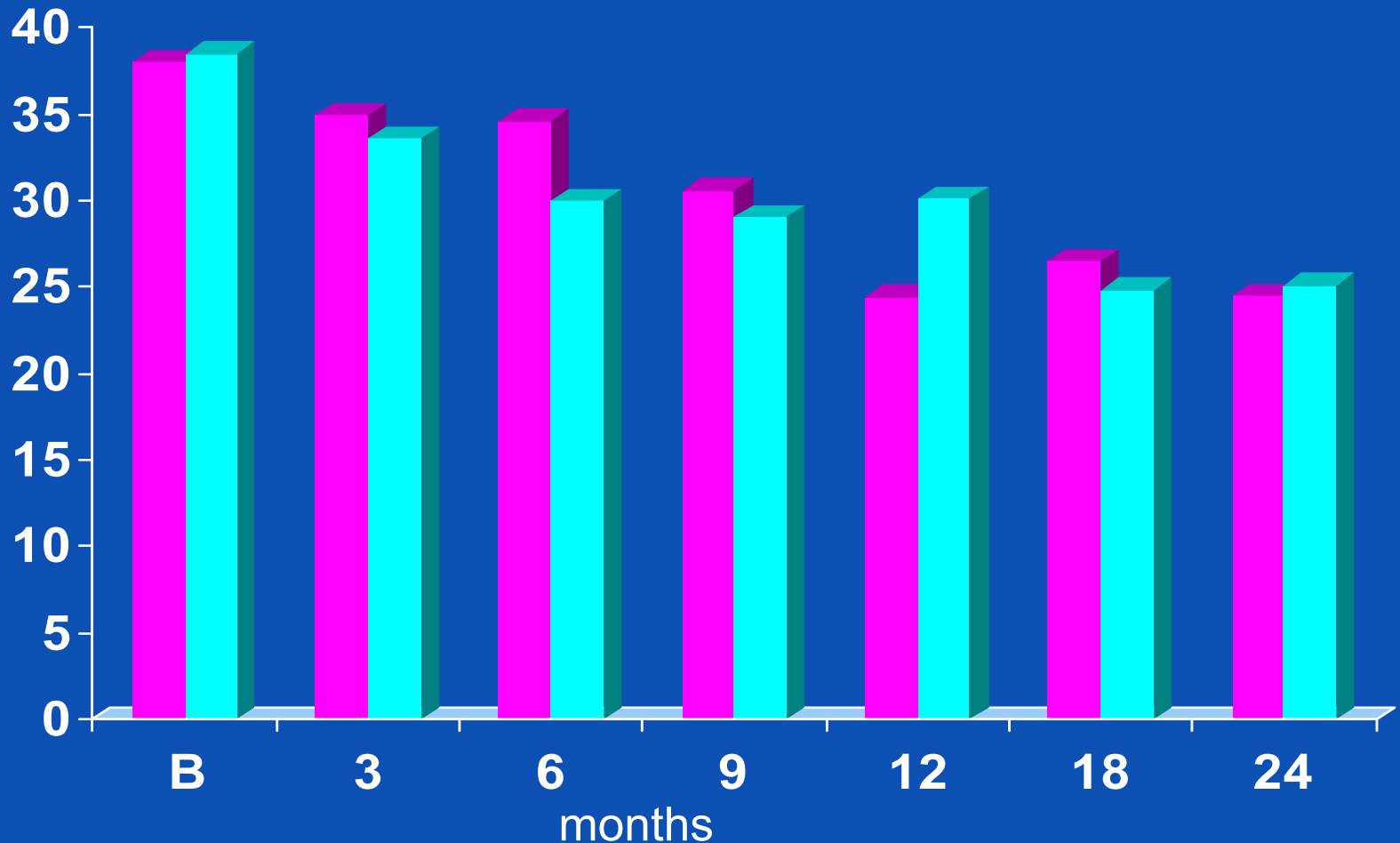


Endocrine subscale mean scores + 95% C.I.s

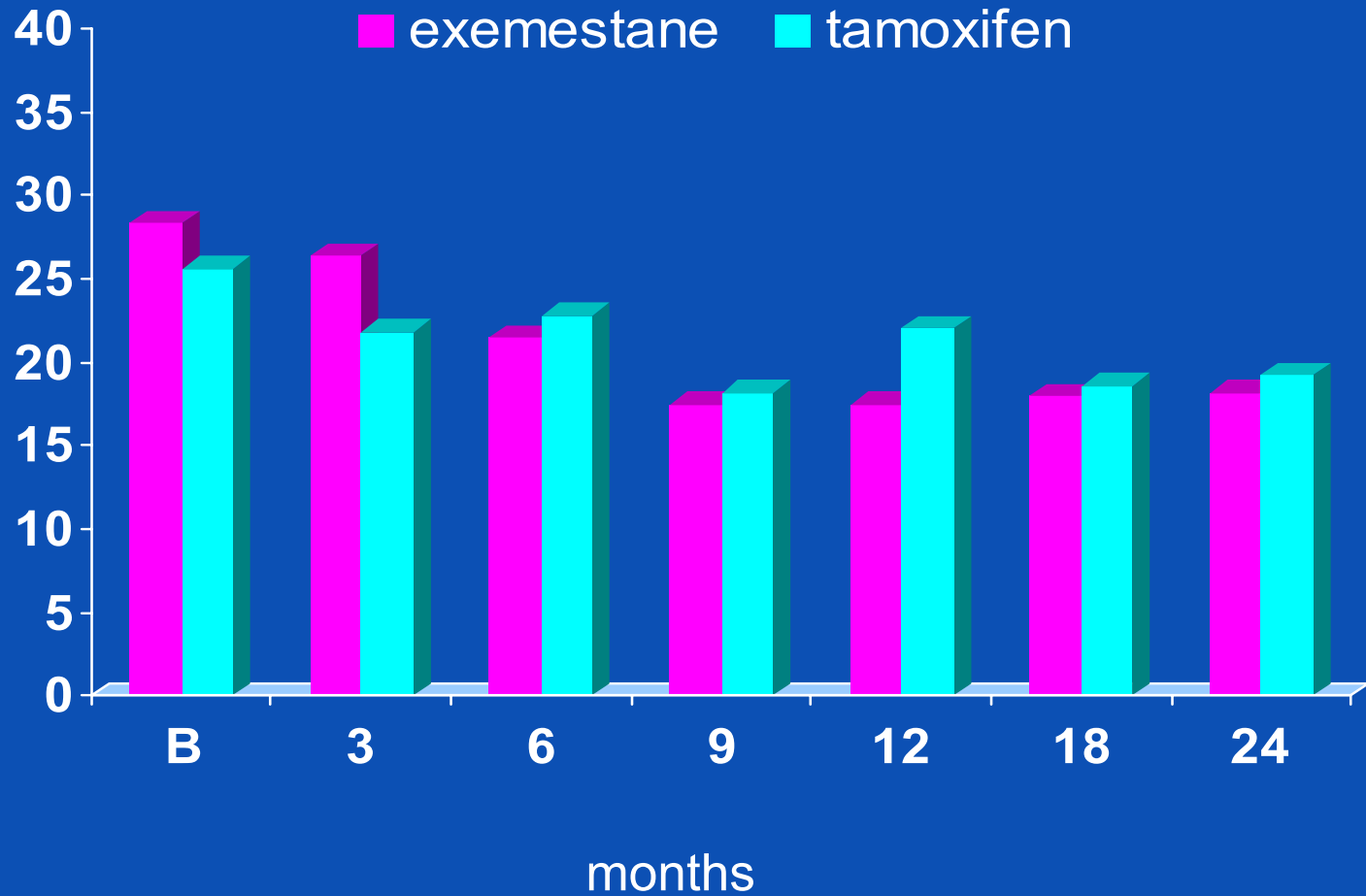


% patients reporting severe hot flushes

■ exemestane ■ tamoxifen

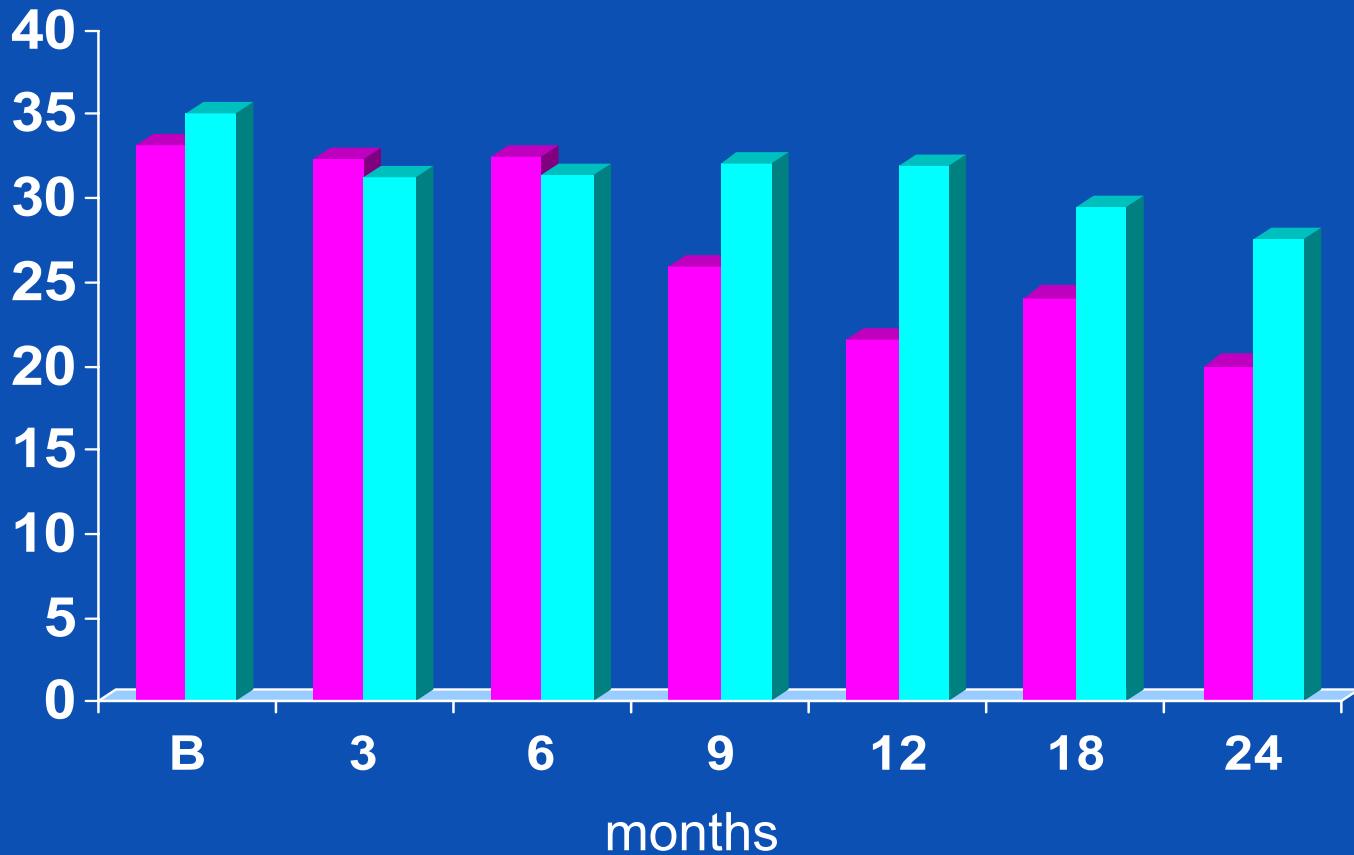


% patients with severe night sweats



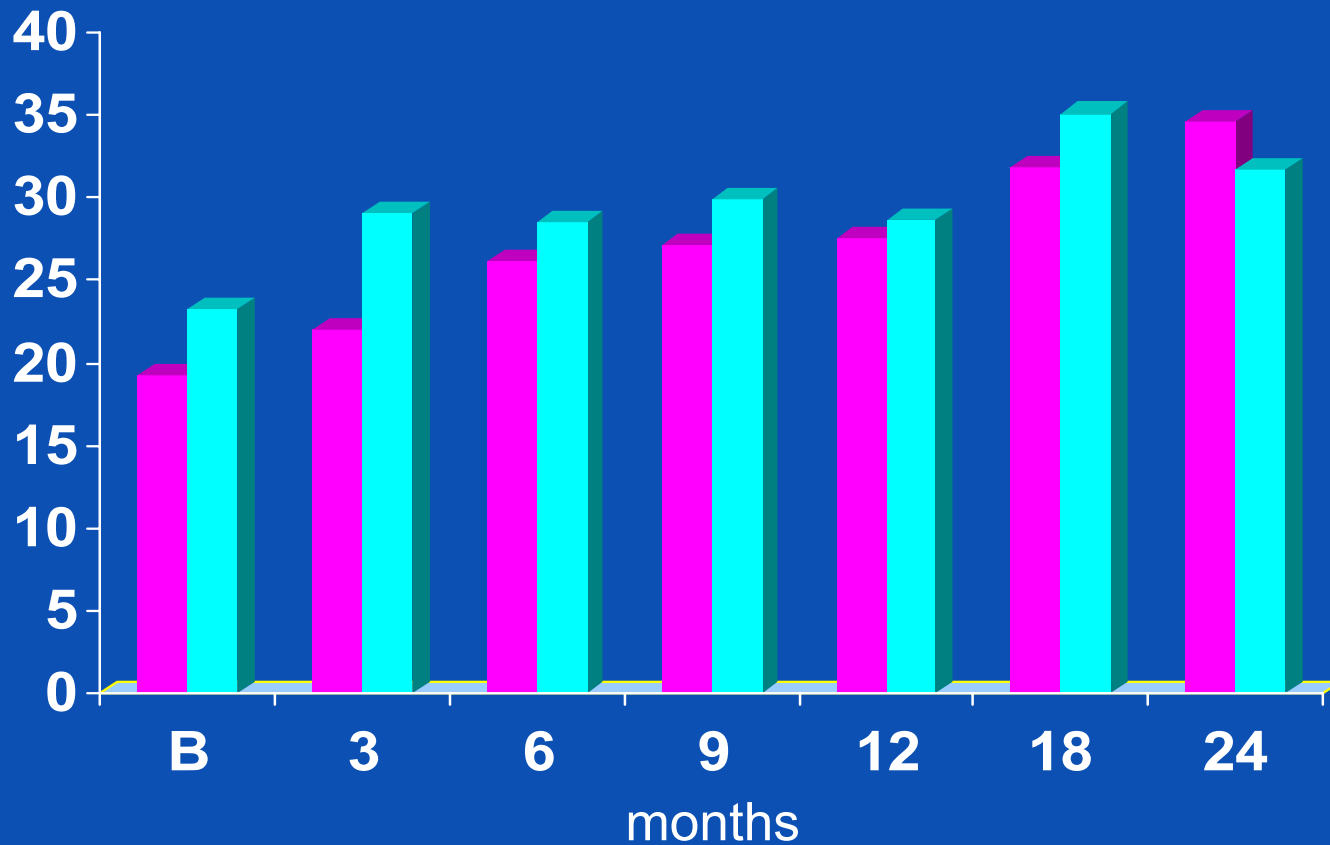
% patients with severe weight gain

■ exemestane ■ tamoxifen

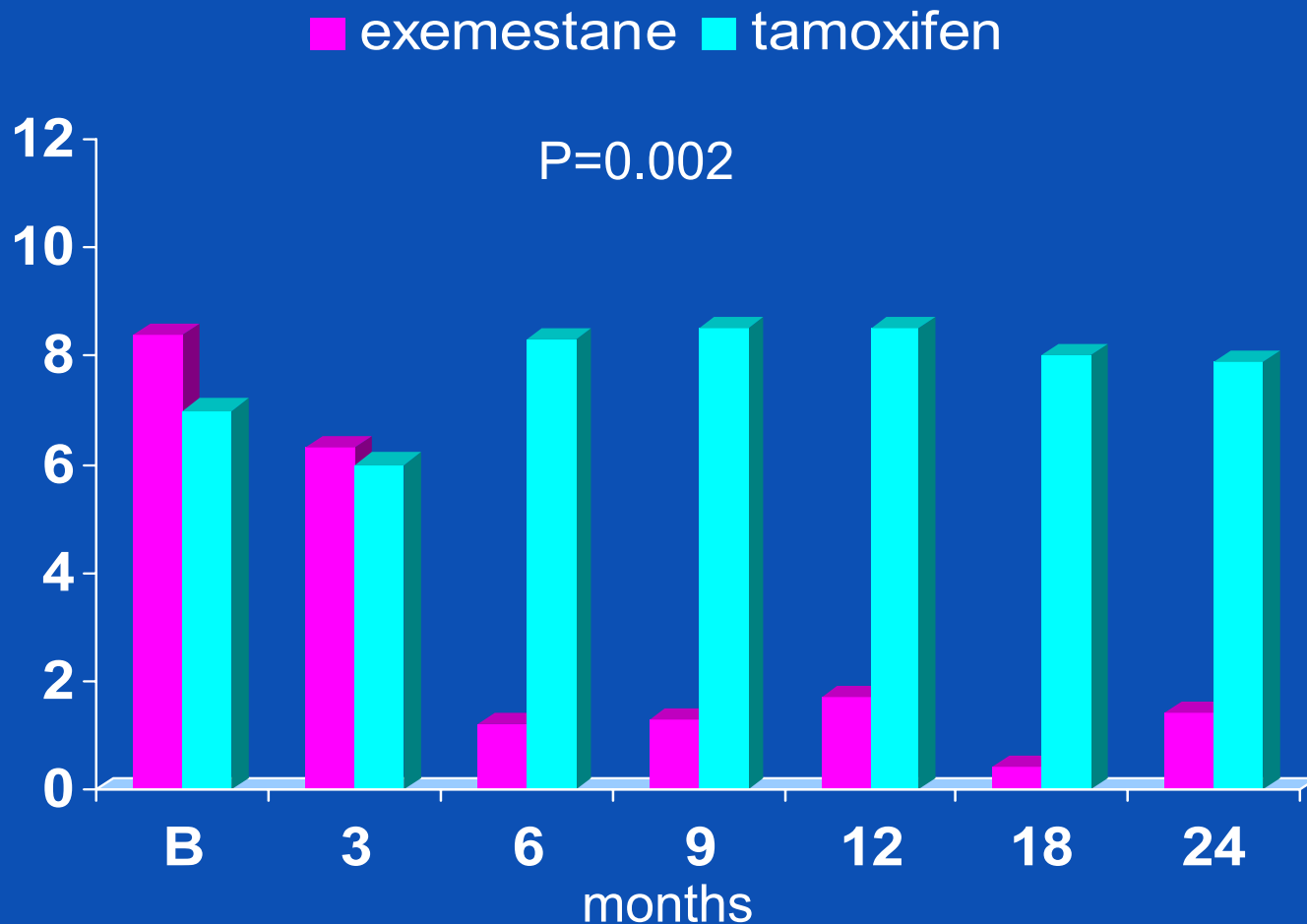


% patients with loss of libido

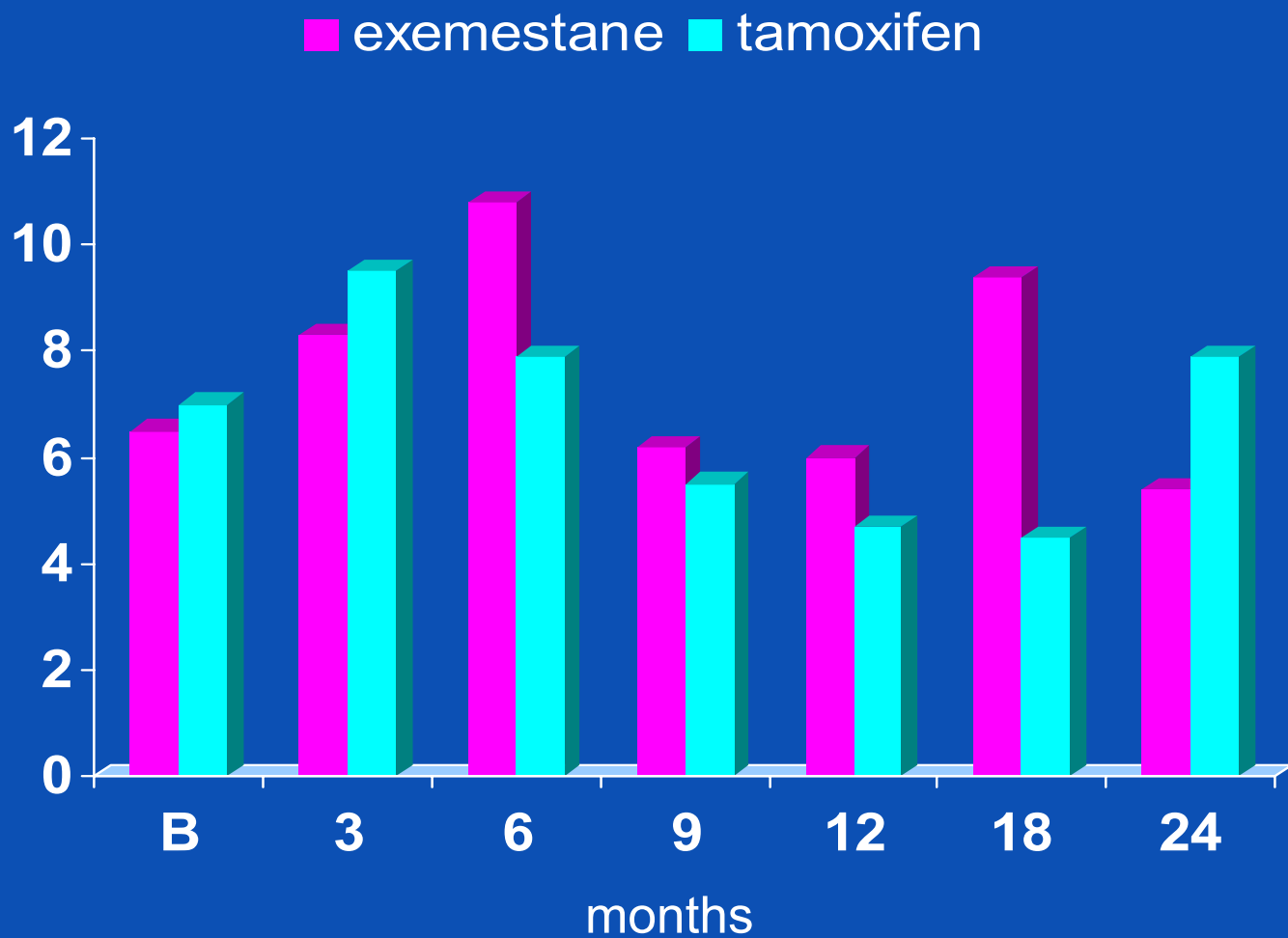
■ exemestane ■ tamoxifen



% patients with severe vaginal discharge



% patients with severe diarrhoea



Summary

- Questionnaire completion was excellent with >87% available at each post baseline visit
- Overall QoL at 2 years was generally good with no significant differences between groups
- Individual symptoms especially vasomotor and sexual complaints remain problematic with all endocrine therapy
- The clinical benefits of exemestane over tamoxifen are achieved without a detrimental impact upon QoL

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CANCER RESEARCH UK 

