

Real-world use of Bacillus Calmette-Guérin (BCG) in patients with high-risk non-muscle invasive bladder cancer (HR-NMIBC)

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Conclusions

- Despite BCG being the standard of care treatment for patients with HR-NMIBC, a substantial proportion of patients did not receive 1L BCG, primarily due to patient refusal and BCG shortages.
- Reluctance to receive a live attenuated vaccine and concern about side effects were common reasons for refusal.
- Fewer than half of patients received guideline recommended adequate BCG. Recurrence rates were higher in patients inadequately treated with BCG.
- Findings underscore an urgent need for effective alternative therapies to BCG and enhanced patient education to mitigate recurrence risk and improve outcomes for patients with HR-NMIBC.



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Background

- BCG is the current gold standard for management of high-risk non-muscle invasive bladder cancer (HR-NMIBC) (1-3), demonstrating significant reductions in recurrence (4) and progression rates across clinical settings (5,6)
- Global guidelines recommend that patients with HR-NMIBC receive BCG induction followed by maintenance therapy for 1 to 3 years (1,2)
- Despite this, a proportion of patients in real-world clinical practice either receive inadequate BCG therapy (defined as <5/6 induction doses and <2/3 maintenance doses) or do not receive it at all (7)

Objective

To identify and characterize factors associated with no or inadequate BCG treatment in patients with HR-NMIBC in real-world clinical practice across global settings

Methods

Study Design

- Data were derived from the Adelphi Disease Specific Programme™ (DSP™), a cross-sectional survey of urologists, medical oncologists, and clinical oncologists (UK only) and their consulting patients (8)
- Physicians completed surveys for eight patients who consecutively consulted with them from July 2023 – April 2024

Participating countries	Number of patients
China	384
Japan	261
Canada	126
France	385
Germany	383
Italy	363
Spain	373
UK	308

Physician inclusion criteria

- Urologists, medical or clinical oncologists actively involved in management of patients with HR-NMIBC
- Spending ≥50% of their professional time in direct patient care
- Managing ≥6 patients with bladder cancer per month

Patient eligibility

- Aged ≥18 years
- With a physician-confirmed diagnosis of HR-NMIBC (with HG Ta/T1, or CIS)
- Diagnosed ≥12 months prior to data collection

BCG, Bacillus Calmette Guérin; CIS, Carcinoma in situ; HG, High grade; HR-NMIBC, high-risk non-muscle invasive bladder cancer

Data collection

- Physicians reported current and retrospective patient data from the patient's chart
- Data on demographics, clinical characteristics, treatments received were included
- All physician and patient data were anonymised and aggregated before analysis

Statistical analysis

- Physician-reported data were stratified by line of therapy and analysed
- Descriptive statistics were used to summarize data
- Mean and standard deviation (SD) were reported for continuous variables; categorical variables were presented as frequency and percentages

Results

BASELINE SOCIODEMOGRAPHIC AND CLINICAL CHARACTERISTICS

- A total of 2583 patients from 8 countries, with a mean (SD) age of 68.9 years (9.77) were included
- Treating physicians were medical oncologists (45%) and urologists (55%)
- Overall, the majority of treating physicians were in academic setting (56%), except for Japan, Canada, and Italy where community settings were more common, with 58%, 48% and 60% respectively
- The mean (SD) time since HR-NMIBC diagnosis to data capture was 26.2 (17.29) months
- At diagnosis, the majority of patients had papillary only disease (83%)

Table 1: Baseline sociodemographic and clinical characteristics

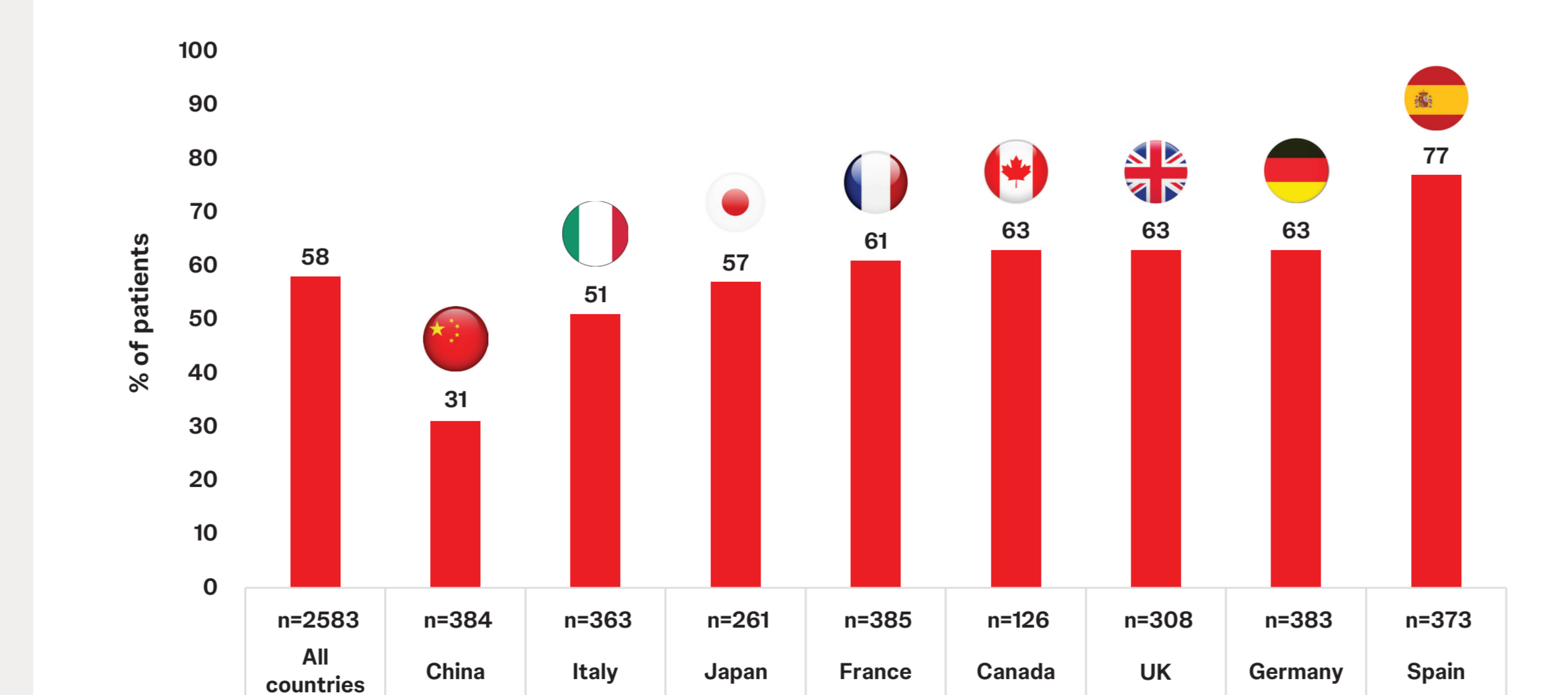
	All countries n=2583	China n=384	Japan n=261	Canada n=126	France n=385	Germany n=383	Italy n=363	Spain n=373	UK n=308
Age, Mean (SD)	68.9 (9.77)	60.9 (10.5)	73.3 (9.37)	72.2 (8.78)	69.9 (9.6)	69.9 (7.33)	69.1 (8.79)	70.6 (9.19)	69.3 (9.19)
Male, n (%)	1920 (74)	291 (76)	213 (82)	92 (73)	290 (75)	306 (80)	242 (67)	292 (78)	194 (63)
Physician's primary specialty, n (%)									
Medical oncologist	1159 (45)	40 (10)	28 (11)	12 (10)	181 (47)	214 (56)	278 (77)	212 (57)	194 (63)
Urologist	1424 (55)	344 (90)	233 (89)	114 (90)	204 (53)	169 (44)	85 (23)	161 (43)	114 (37)
Physician's primary practice setting, n (%)									
Academic hospital	1440 (56)	325 (85)	82 (31)	44 (35)	156 (41)	164 (43)	119 (33)	323 (87)	227 (74)
Community hospital	694 (27)	0 (0)	151 (58)	60 (48)	177 (46)	24 (6)	216 (60)	42 (11)	24 (8)
Office	338 (13)	46 (12)	0 (0)	28 (22)	53 (14)	195 (51)	0 (0)	16 (4)	0 (0)
Specialist Cancer	136 (5)	13 (3)	28 (11)	0 (0)	15 (4)	0 (0)	23 (6)	0 (0)	57 (19)
Time from diagnosis and data capture, months	n=2388	n=371	n=246	n=122	n=344	n=374	n=328	n=360	n=243
Mean (SD)	26.2 (17.29)	25.8 (12.13)	31.5 (26.09)	38.3 (29.29)	25.7 (15.61)	22.2 (9.53)	26.8 (18.11)	25.2 (17.42)	22.6 (9.18)
Tumour type at diagnosis	n=2583	n=384	n=261	n=126	n=385	n=383	n=363	n=373	n=308
CIS only	201 (8)	26 (7)	2 (1)	7 (6)	29 (8)	42 (11)	18 (5)	49 (13)	9 (3)
CIS + Papillary	247 (10)	30 (8)	48 (18)	28 (22)	56 (15)	26 (7)	23 (6)	15 (4)	21 (7)
Papillary only	2135 (83)	328 (85)	192 (74)	91 (72)	300 (78)	315 (82)	322 (89)	309 (83)	278 (90)

SD, Standard deviation

FIRST-LINE (1L) BCG USAGE

- Overall, 58% of patients received 1L BCG treatment. Additional country data is shown in Figure 1
- Other 1L treatments received included intravesical chemotherapy (15%) and transurethral resection of bladder tumour (20%)
- Highest proportion of patients receiving 1L BCG was observed in Spain (77%), while the lowest was in China (31%)

Figure 1: 1L BCG utilisation among HR-NMIBC patients

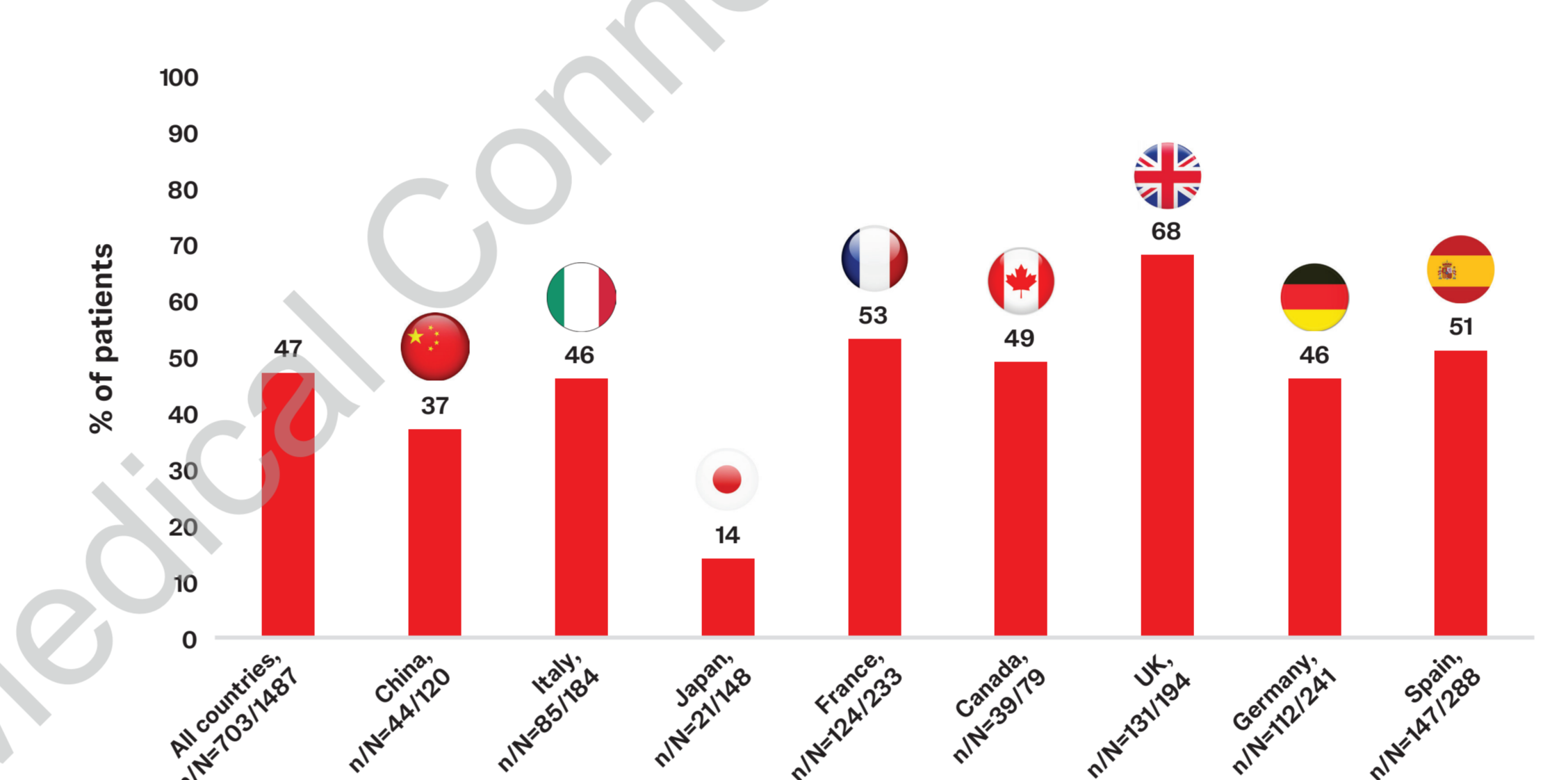


1L, First-line; BCG, Bacillus Calmette Guérin; HR-NMIBC, high-risk non-muscle invasive bladder cancer; TURBT, transurethral resection of bladder tumour

ADEQUATE¹ BCG USAGE

- Of patients receiving 1L BCG (n = 1487), 47% received adequate BCG (> 5/6 induction instillations and 2/3 maintenance instillations)
- The lowest rate of adequate BCG treatment was reported in Japan (14%), with the highest rate reported in the UK (68%)

Figure 2: Adequate¹ BCG usage



¹Adequate BCG was defined as ≥ 5/6 induction instillations and 2/3 maintenance instillations
 1L, First-line; BCG, Bacillus Calmette Guérin

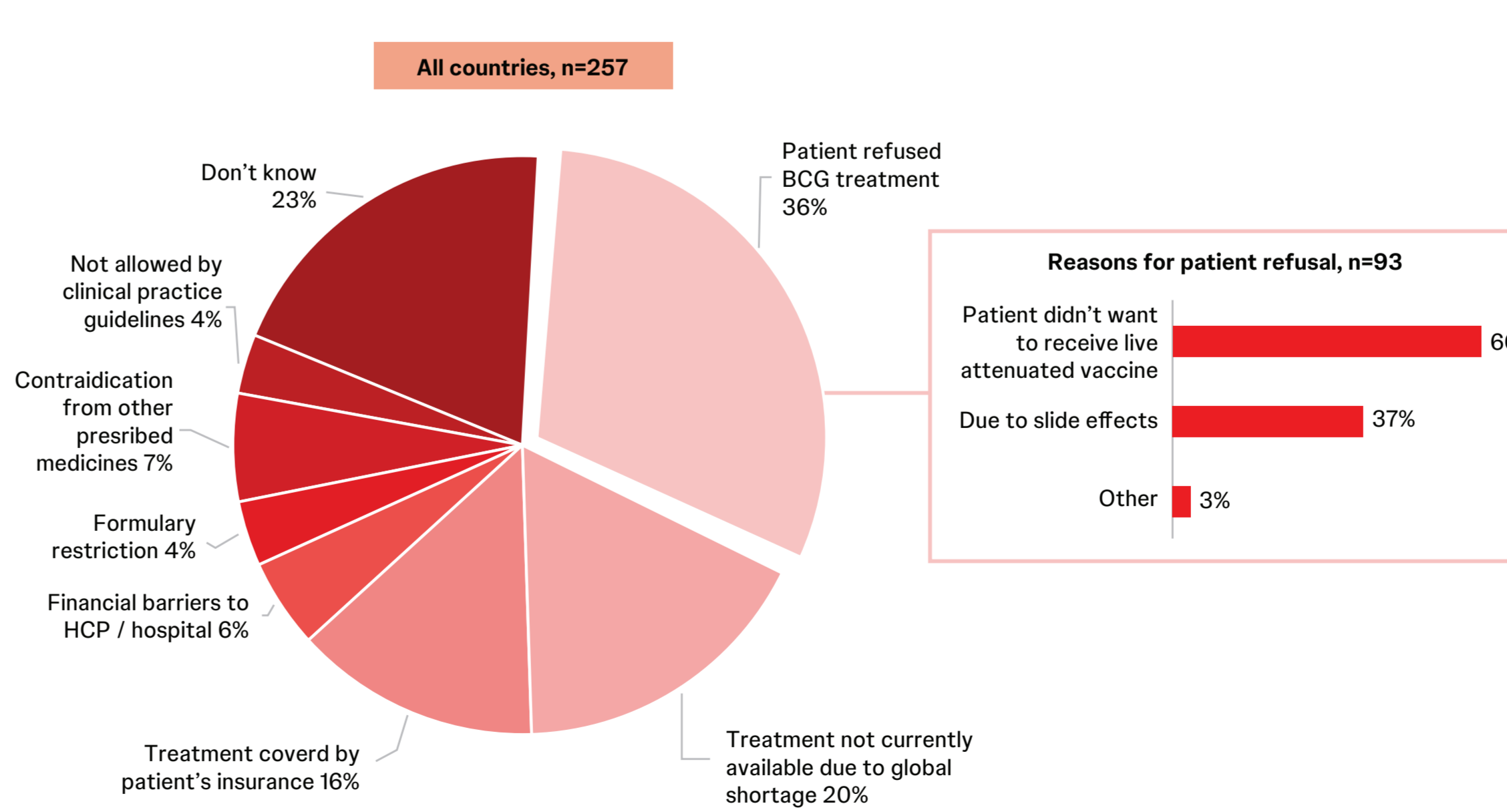
EARLY BCG DISCONTINUATION

- Overall (n=194), 15% of patients discontinued BCG treatment early (ranging from 10% in Japan to 24% in Canada)
- Common reasons for early discontinuation were disease recurrence (range, UK: 21% - China: 55%), patient request to stop (range, China: 9% - Canada: 47%) and unacceptable tolerability (range, Germany: 29% - Japan: 86%)

OVERALL BCG NON-USAGE

- Of the 1096 patients who did not receive 1L BCG, physicians reported reasons for non-use in 257 patients
- Of the 257 patients with additional information on BCG non-use, the most common reasons were patient refusal (n = 93, 36%) and BCG unavailability due to global shortages (n = 45, 20%)
 - Patient refusal was the most common reason for BCG non-use in Germany (58%), Japan (50%), and China (43%)
 - Unavailability due to global shortage was the major reason for BCG non-use in the UK (65%) and France (42%)
- Among patients who refused treatment (n=93), the primary reasons were reluctance to receive a live attenuated vaccine (60%) and concern about side effects (37%)

Figure 3: Physician-reported reasons for BCG non-usage as 1L treatment



1L, First-line; BCG, Bacillus Calmette Guérin

IMPACT OF BCG SHORTAGE ON TREATMENT PATTERNS IN 1L HR-NMIBC

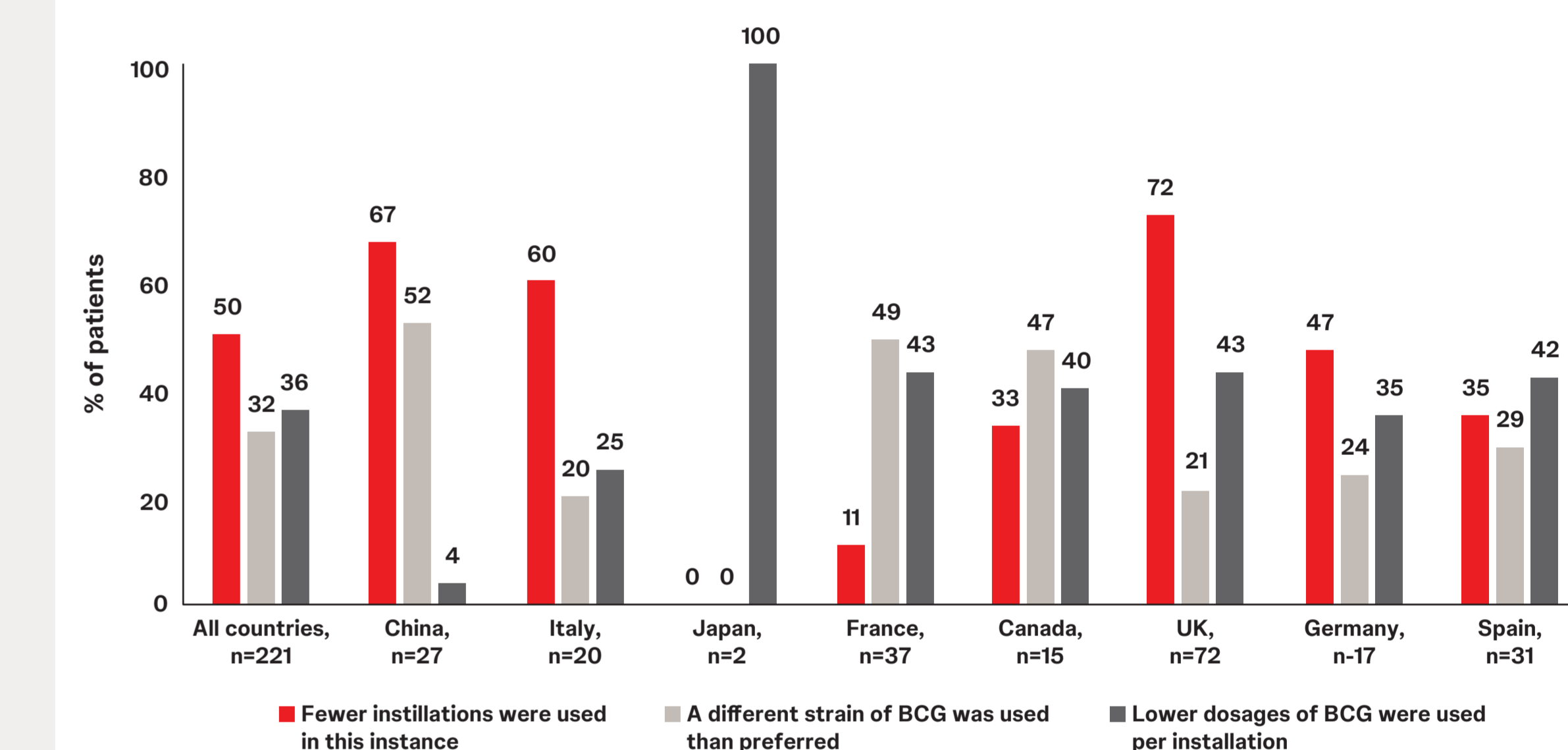
- Of 1313 patients who received 1L BCG and had further treatment details, 221 (17%) were impacted by BCG shortage; primarily in the UK (40%), China (28%), and Canada (21%)
- Overall, BCG shortage led to the use of fewer instillations (50%), a different strain of BCG was used than preferred (32%), and lower dosages of BCG were used per instillation (36%)

Table 2: Impact of BCG shortage on patients who received 1L BCG

Impacted by BCG shortage	All countries	China	Italy	Japan	France	Canada	UK	Germany	Spain
n/N	221/1092	27/70	20/132	2/144	37/185	15/56	72/108	17/169	31/228
%	17%	28%	13%	1%	17%	21%	40%	9%	12%

1L, First-line; BCG, Bacillus Calmette Guérin; SD, Standard deviation

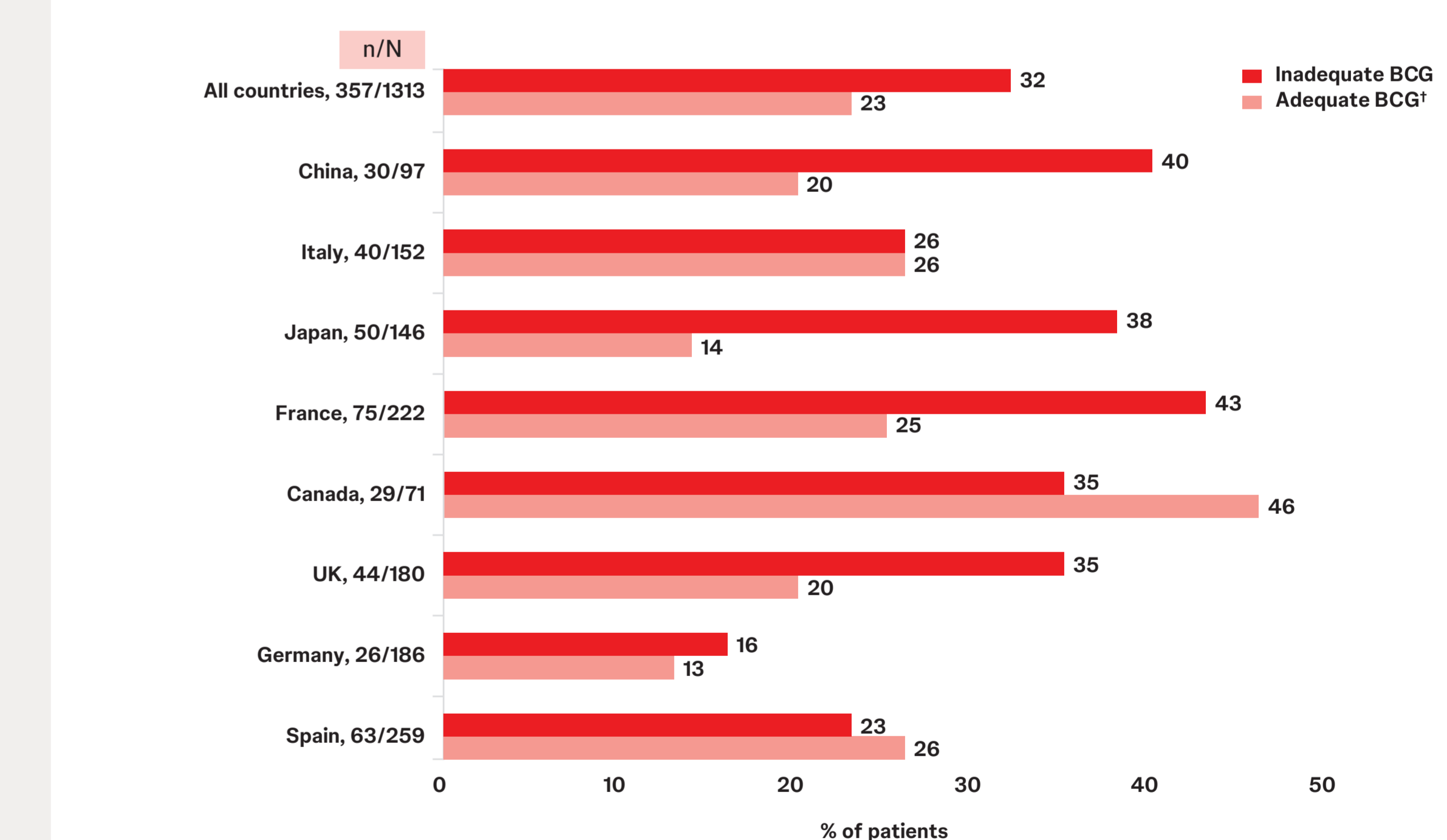
Figure 4: Effect of BCG shortages on treatment patterns of patients who received 1L BCG



RECURRENCE RATES AFTER 1L BCG

- Overall, recurrence after 1L BCG (n=1313) occurred in 23% of patients with adequate BCG and 32% of patients with inadequate BCG treatment with a mean (SD) of 26.2 (17.29) months from initial diagnosis to data collection

Figure 5: Recurrence rates after 1L BCG



¹Adequate BCG was defined as ≥ 5/6 induction instillations and 2/3 maintenance instillations
 1L, First-line; BCG, Bacillus Calmette Guérin

Limitations

- This analysis is limited by the retrospective, cross-sectional nature of the Adelphi DSP
- Some patient record forms had missing data, which was not imputed, and these patients were excluded from analyses
- Participating patients may not reflect the general HR-NMIBC patient population since the DSP only includes patients who are consulting with their physician. This means that patients who consult more frequently have a higher likelihood of being included

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