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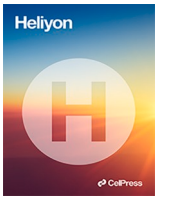

Research article

Comparison of efficacy and safety between daptomycin plus β-lactam and daptomycin monotherapy for bloodstream infections due to gram-positive cocci: A systematic review and meta-analysis

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ABSTRACT

Objectives: We performed a comprehensive systematic review and meta-analysis to evaluate the clinical or microbiological outcomes and safety of a combination of daptomycin (DAP) and β-lactams compared to DAP monotherapy in patients with blood stream infection (BSI) due to gram-positive cocci (GPC).

Methods: We searched Scopus, PubMed, EMBASE, CINAHL, and Ityuushi databases up to January 30, 2023. Outcomes included all-cause mortality, clinical failure, and creatine phosphokinase (CPK) elevation.

Results: Six cohorts or case-control studies fulfilled the inclusion criteria and were included in the final meta-analysis. Combination therapy of DAP and β-lactams significantly reduced the mortality and clinical failure rate for all BSI due to GPC compared with the DAP monotherapy (mortality, odds ratio [OR] = 0.63, 95 % confidence interval [CI] = 0.41–0.98; clinical failure, OR = 0.42, 95 % CI = 0.22–0.81). In contrast, no significant difference was noted in the incidence of CPK elevation between the two groups (OR = 0.85, 95 % CI = 0.39–1.84).

Conclusion: Altogether, combination therapy of DAP and β-lactams can improve the prognosis for patients with BSI due to GPC compared with DAP alone. Therefore, it should be considered as an option for the empirical treatment of BSI caused by GPC.

1. Background

Bloodstream infections (BSI) are life threatening. Approximately half (46.8 %) of the cases are caused by *Staphylococcus aureus*, followed by gram-positive cocci (GPC) such as *Staphylococcus epidermidis*, *Streptococcus pneumoniae*, and *Enterococcus* spp [1]. Especially, multidrug-resistant bacteria, such as methicillin-resistant *S. aureus* (MRSA), vancomycin-resistant enterococci (VRE), and β-lactamase-resistant *S. pneumoniae*, have attracted increasing attention as the infections require immediate treatment [2].

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Abbreviations list

Blood stream infection BSI
gram-positive cocci GPC
methicillin-resistant Staphylococcus aureus MRSA
vancomycin-resistant enterococci VRE
daptomycin DAP
vancomycin VCM
randomized controlled trial: RCT retrospective and cohort studies
CSs creatine phosphokinase
CK unadjusted risk ratios
RRs odds ratios
ORs confidential intervals

Daptomycin (DAP) and vancomycin (VCM) are widely used as first-line antimicrobials against several infections (e.g., infective endocarditis, bone and joint infections, skin and soft tissue infections, and bacteremia) caused by GPC [3–6]. In patients with BSI caused by MRSA, DAP therapy has demonstrated a lower risk of clinical failure and treatment-limiting adverse events than VCM therapy [7–9]. However, as the prevalence of VRE- and VCM-resistant *S. aureus* (VRSA) has increased [10], DAP-resistant GPC has recently emerged [11], emphasizing the need to consider the limitations of DAP monotherapy.

The use of β-lactam as a combination therapy with anti-MRSA drugs can enhance the antibacterial activity against anti-MRSA drug-non-susceptible GPC (e.g. VRE, VRSA, DAP-resistant Enterococci and DAP-resistant *S. aureus*) isolated from patients with BSI [12,13]. Therefore, several meta-analyses have been performed to study whether a combination therapy of anti-MRSA drug plus β-lactams could improve clinical outcomes. They have reported that VCM or DAP plus β-lactams therapies improved microbial outcome such as Sustained detection of bacteria from sterile specimens, but not mortality in patients with BSI due to MRSA, compared with VCM or DAP monotherapy [14–17]. VCM is associated with a higher incidence of renal dysfunction than DAP, and dose adjustment could be difficult in certain situations, such as during severe infections or when renal function is impaired [18,19]. This implies that the use of VCM should be avoided under several situations, and instead a combination therapy with DAP should be considered. However, most combination and monotherapy groups in previous meta-analyses used VCM and the proportion of the patients treated with DAP was small, thereby making it challenging to evaluate whether the combined DAP with β-lactam therapy is more effective than DAP alone.

Therefore, we conducted a comprehensive systematic review and meta-analysis to determine whether a combined therapy of DAP with β-lactams could improve clinical or microbiological outcomes and safety compared to DAP monotherapy in patients with bloodstream infections caused by GPC.

2. Methods

2.1. Date sources and search strategy

This study was conducted according to the PRISMA guidelines for reporting systematic reviews and meta-analyses (PRISMA checklist) [20]. We systematically searched relevant articles written in the English and Japanese languages in Scopus, PubMed, EMBASE, CINAHL, and Ityuushi databases databases up to January 30, 2023, using the following terms: “daptomycin,” “combinable,” “combinated,” “combination,” “combinational,” “combinations,” “combinative,” “combine,” “combined,” “combines,” “combining,” “beta-lactams,” “beta,” “lactams,” “beta lactams,” “lactams,” “lactam,” “beta lactam, “cephalosporine,” “cephalosporines,” “cephalosporins,” “cephalosporin,” “benzylpenicillins,” “penicillin g,” “benzylpenicillin,” “penicillin,” “penicillines,” “penicillins.” The following PICO criteria were used for study selection: patient population (P), patients with BSI due to GPC; intervention (I), combination therapy of DAP and β-lactams; comparison (C), DAP monotherapy, outcome (O), overall mortality, clinical failure, and creatine phosphokinase (CK) elevation.

2.2. Study selection

First, titles and abstracts were independently screened by two individuals (TU and HK) to exclude irrelevant articles. Next, full-text articles were reviewed based on the inclusion and exclusion criteria, and articles for the final qualitative synthesis and meta-analysis were identified [21]. Disagreements were resolved through arbitration by a third investigator (MH). If the original publication did not include sufficient information about the outcomes, additional data were requested from the corresponding authors via e-mail. Studies were excluded if they did not provide information on each antimicrobial agent, or if the authors were unable to provide such data upon request. Randomized controlled trials (RCTs) and retrospective and cohort studies (CSs) reporting mortality, clinical failure, and CPK elevation in patients treated with combination therapy and DAP monotherapy for BSI due to GPC were included. The targeted patients were defined as adults with GPC bacteremia confirmed by blood culture.

2.3. Data extraction and quality assessment

Relevant data extracted from the studies included authors, publication year, study design and period, drug regimens for each antimicrobial agent, clinical response, treatment duration, demographic features (age), and patient population. The Newcastle–Ottawa Quality Assessment Scale [22] was used to evaluate the quality of CSs.

2.4. Definitions of efficacy and safety

The time to follow-up was based on the definition used in each study. The intention-to-treat (ITT) population was defined as all randomized patients in the RCTs and the clinically evaluable population who had been administered combination therapy or DAP monotherapy according to the study protocol and had undergone an assessment of clinical response. The primary outcome was overall mortality. The secondary outcome was clinical failure and evaluation of CPK evaluation. Clinical failure was defined as the worsening or new/recurrent signs and symptoms, persistent positive culture results or BSI recurrence, including death. CPK level was defined as above the normal upper limit. Moreover, sensitivity analysis was performed to investigate each outcome.

2.5. Statistical analysis

Based on a previous study [23], a meta-analysis was conducted using Review Manager (RevMan Web Version 4.12.0. The Cochrane Collaboration, 2022. Available from: Revman Cochrane.org). Statistical heterogeneity between studies was evaluated by a χ^2 test. I^2 was used to denote the degree (0–25 %, low heterogeneity; 25–50 %, moderate heterogeneity; 50–75 %, substantial heterogeneity; 75–100 %, considerable heterogeneity). Significant heterogeneity was defined as a p-value of <0.1 or $I^2 > 50$ %. Fixed- and random-effects models were applied when data were considered homogeneous or heterogeneous, respectively. Unadjusted risk ratios (RRs), odds ratios (ORs), and 95 % confidence intervals (CIs) were calculated for combination therapy and DAP monotherapy for each study. The pooled RRs or ORs and 95 % CIs were calculated using a fixed-effects model (Mantel–Haenszel method) and a

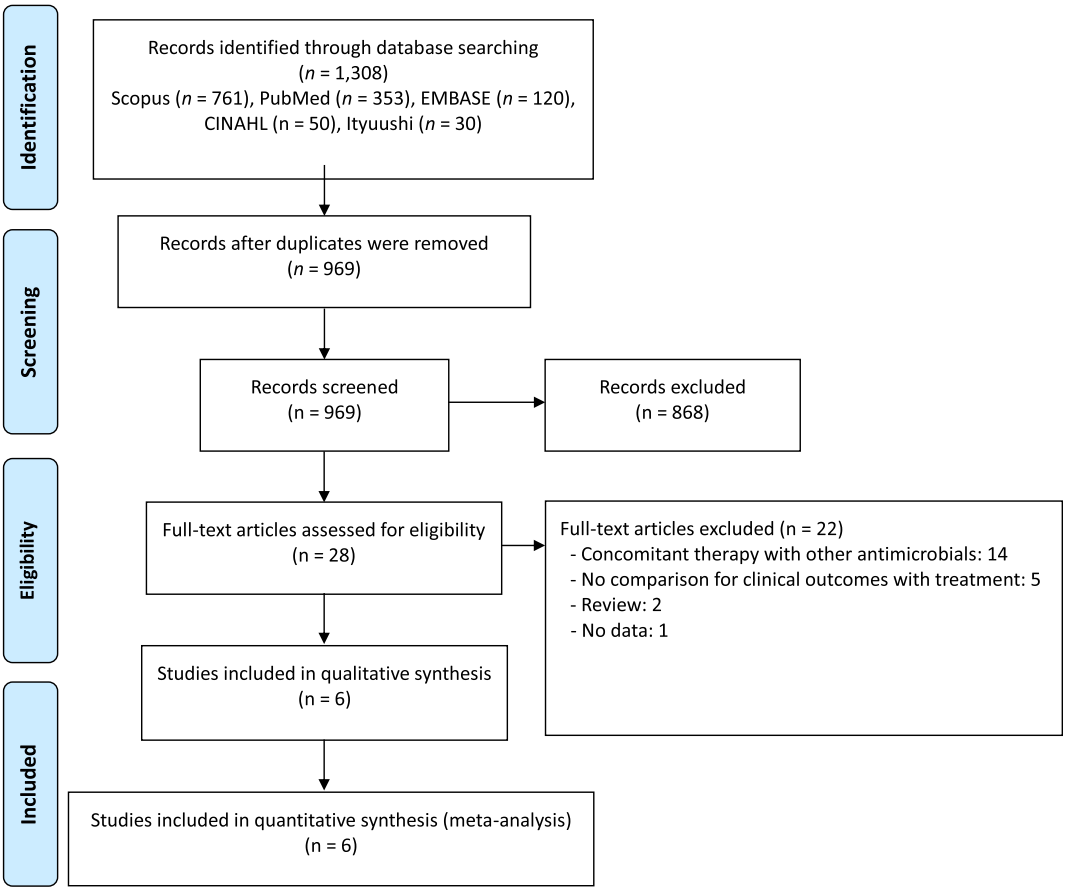

Fig. 1. PRISMA flow diagram for the selection of eligible studies. This figure depicts the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flowchart. Scopus, PubMed, EMBASE, CINAHL, and Ityuushi databases were searched for relevant words until January 30, 2023.

random-effects model (DerSimonian and Laird method), and the RRs or ORs from these results were compared.

3. Results

3.1. Systematic review

Fig. 1 illustrates the study selection process. The extracted research retrieved 1308 publications. After duplicates were removed, the number of publications was 969. The titles and abstracts were screened to exclude irrelevant studies, resulting in 28 potentially eligible studies. Eventually, six CSs fulfilled the inclusion criteria and were included in the final meta-analysis. The characteristics of these studies are summarized in Table 1. The included studies were conducted in the USA [24,25,27,28] and Taiwan [26,29]. The Newcastle–Ottawa Quality Assessment Scale scores were relatively moderate or high, ranging from 5 to 7 (Table S1). Data from 844 patients from six CSs were extracted. The number of patients treated with a combination therapy of DAP and β-lactams was 574, whereas 270 patients were treated with DAP monotherapy. The pathogens that cause BSI are MRSA [25,27,28], VRE [26,29], and MRSA or MSSA [24]). Three of the six reports had a median DAP dose of 8 mg/kg or higher [27–29]. The rest were 6.0 mg/kg, 7.6 mg/kg, and 7.8 mg/kg [24–26]. None of the reports found significant dose differences between the DAP and β-lactams group and the DAP monotherapy group. The β-lactam antibiotics in the combination therapy included ceftaroline [25,27], largely cefepime or cefazolin [28], penicillins, cephalosporins, or carbapenems [26,29]. Details of one report were unavailable [24] (Table 1).

4. Meta-analysis

4.1. Mortality

Mortality was extracted from five CSs [25–29] and analyzed overall [25] at the end of DAP treatment [26], within 30 days [27], within 60 days [28], and within 28 days [29]. The combination therapy of DAP and β-lactams significantly improved mortality in

Table 1
Characteristics of studies included in the meta-analysis.

Author	Study design period	Pathogen of BSI	DAP dosage (mg/kg) median (range or IQR)	Combination of β-lactams	No. of patients (combination vs. monotherapy)	Treatment duration (median, days)	Age (mean, years)	Outcomes	NOQA Scale
Moise et al. (2013) [24]	MC, RC Jan 2003 to Dec 2009	MSSA (30.0 %) or MRSA (70.0 %)	6.0 (range: 3–10)	NR	30 vs. 50	11	NR	CE	5
Cortes-Penfield et al. (2018) [25]	SC, RC Jan 2012 to Jun 2015	MRSA	7.6 (range: 5.7–13.8)	Ceftaroline	5 vs. 4	36	65 vs. 62	MO	6
Chuang et al. (2018) [26]	MC, RC Jan 2010 to Jul 2015	VRE	7.8 (IQR; 6.8–8.7)	Penicillins (11.5 %), Cephalosporins (47.1 %), Carbapenems (70.1 %)[a]	87 vs. 27	9	63 vs. 68	MO, AE	5
Morrisette et al. (2020) [27]	SC, RC Jan 2007 to Jun 2019	MRSA	combination 9.9 (IQR: 8.8–9.8) monotherapy 9.0 (IQR: 8.4–9.9)	Ceftaroline	15 vs. 14	Combination 40 Monotherapy 42	41 vs. 36	MO, AE	5
Jorgensen et al. (2020) [28]	MC, RC Jan 2008 to Dec 2018	MRSA	8.3 (range: 6.8–9.9)	Mainly cefepime (43.1 %) or cefazolin (25.0 %)	72 vs. 157	10	58 vs. 58	MO, CE, AE	7
Chuang et al. (2022) [29]	MC, RC Jan 2020 to Dec 2021	VRE	≥8 mg/kg	Penicillins (14.0 %), cephalosporins (53.5 %), carbapenems (63.1 %)[a]	45 vs. 385	2.3	68 vs. 67	MO, AE	6

MC, multicenter; SC, single center; RC, retrospective cohort; IQR, interquartile range; DAP, daptomycin; MSSA, methicillin-susceptible staphylococcus aureus; MRSA, methicillin-resistant staphylococcus aureus; VRE, vancomycin-resistant enterococci; CE, clinical evaluation; MO, mortality; AE, adverse effect; NOQA Scale, Newcastle–Ottawa Quality Assessment Scale.

[a] Patients might receive more than one class of β-lactams.

patients with BSI due to GPC, compared with DAP monotherapy (OR = 0.63, 95 % CI = 0.41–0.98, heterogeneity $p = 0.43$, Fig. 2A). The subgroup analysis demonstrated that the combination therapy did not improve mortality due to MRSA [25,27,28] and VRE [26,29], compared with the DAP monotherapy (MRSA, OR = 0.47, 95 % CI = 0.21–1.06, heterogeneity; $p = 0.39$, Fig. 2B; VRE, OR = 0.73, 95 % CI = 0.43–1.22, heterogeneity $p = 0.26$, Fig. 2C).

4.1.1. Clinical failure

A significantly decreasing rate of clinical failure was detected among patients treated with combination therapy of DAP and β-lactams compared with DAP monotherapy in two CSs against BSI due to GPC [24,28,29] (OR = 0.42, 95 % CI = 0.27–0.66, heterogeneity; $p = 0.89$, Fig. 3A). In a subgroup analysis with two CSs for BSI due to MRSA [24,28], the combination therapy significantly reduced the rate of clinical failure, compared with the DAP monotherapy (OR = 0.46, 95 % CI = 0.23–0.89, heterogeneity; $p = 0.31$, Fig. 3B).

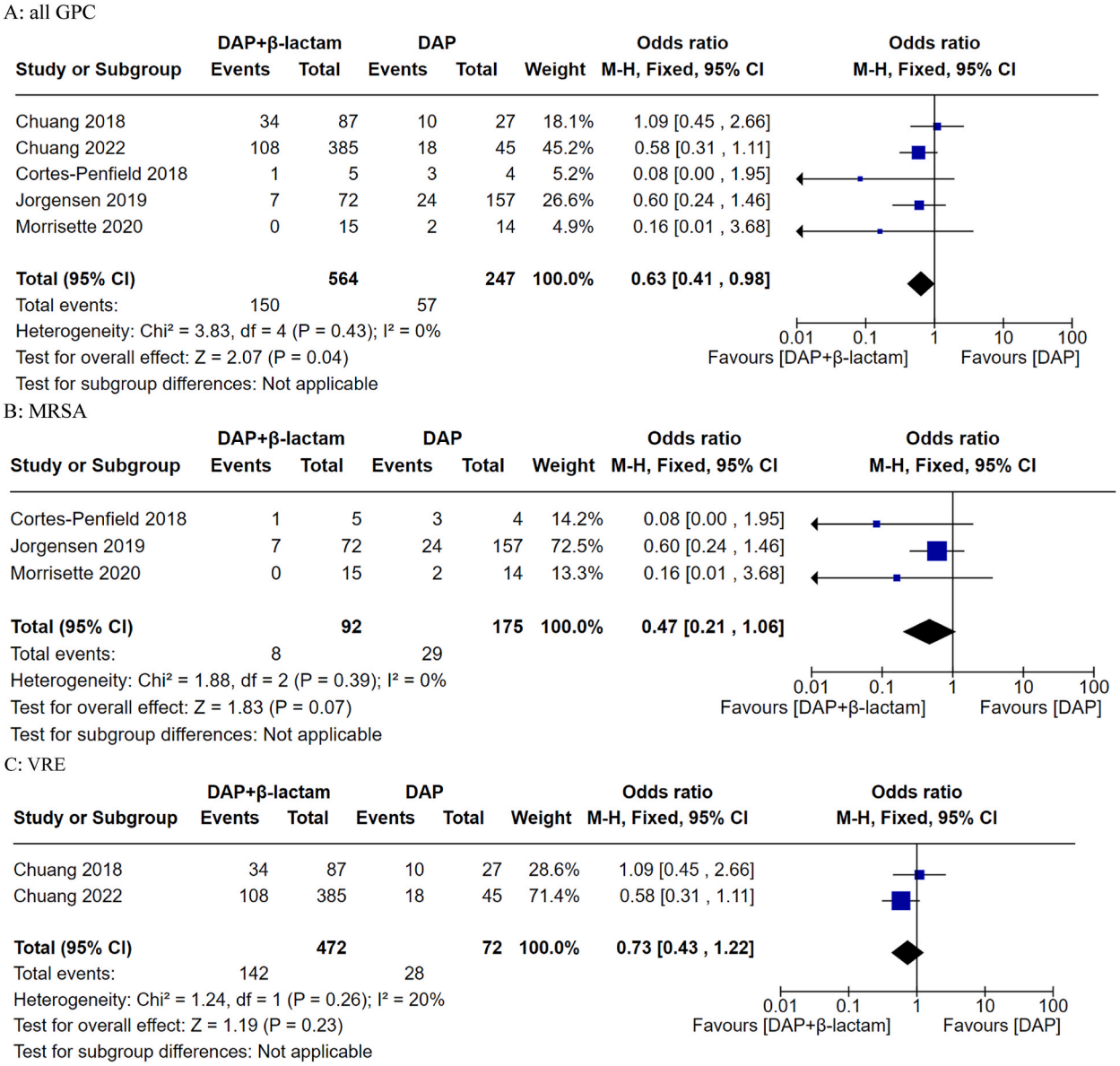

Fig. 2. Forest plot of the odds ratio for mortality between patients with bloodstream infection due to gram-positive cocci treated with DAP pus β-lactams or DAP monotherapy. This figure meta-analyzed mortality between patients with bloodstream infection due to gram-positive cocci treated with DAP pus β-lactams or DAP monotherapy. (a) GPC, (B) MRSA, (C) VRE.

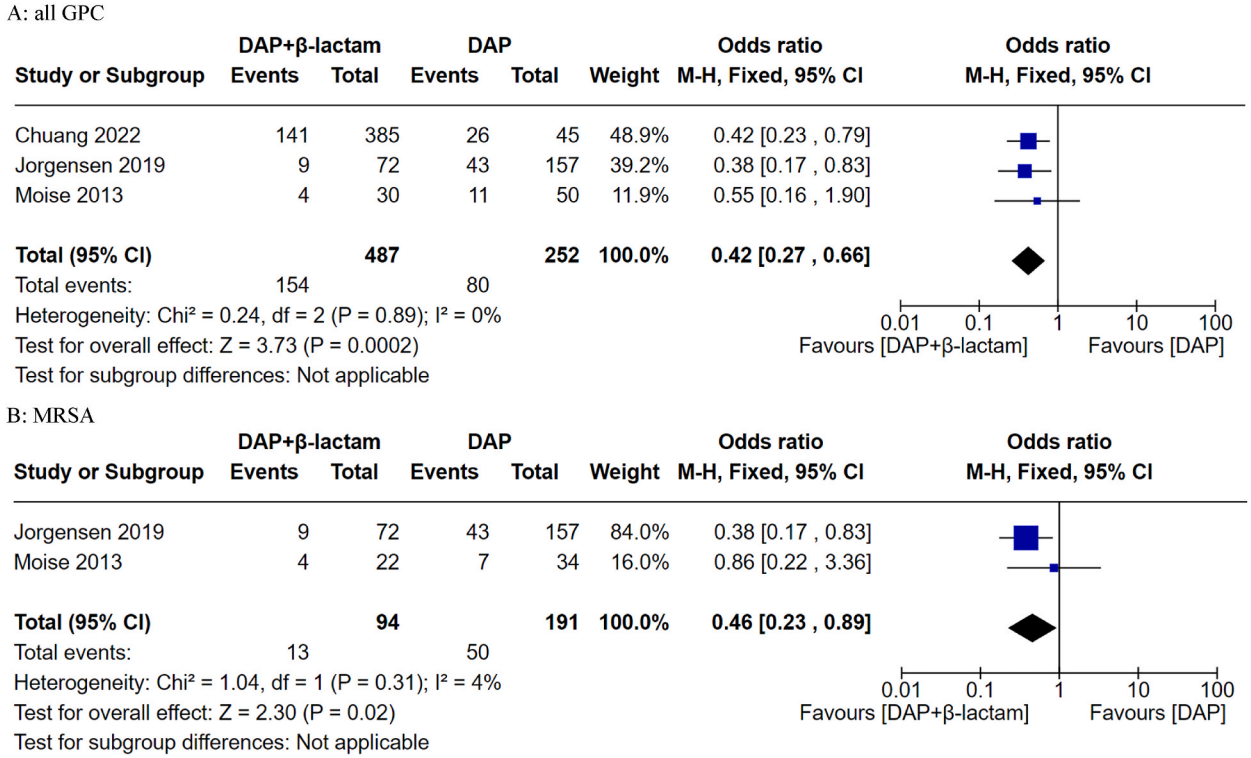

Fig. 3. Forest plot of the odds ratio for clinical failure between patients with bloodstream infection due to gram-positive cocci treated with DAP pus β-lactams or DAP monotherapy. This figure meta-analyzed clinical failure between patients with bloodstream infection due to gram-positive cocci treated with DAP pus β-lactams or DAP monotherapy. (A) GPC and (B) MRSA.

4.1.2. Adverse events

Four CSs reported elevated CPK elevation [26–29]. The incidence of CPK elevation was not significantly different between the combination therapy and DAP monotherapy (OR = 0.85, 95 % CI = 0.39–1.84, heterogeneity; $p = 0.85$, Fig. 4).

5. Discussion

Our meta-analysis demonstrated that combination therapy of DAP with β-lactams reduced mortality and clinical failure than DAP monotherapy for patients with BSI due to GPC. This is the first study to evaluate the usefulness of a pure DAP and β-lactam combination without VCM. Previous meta-analyses that compared a combination of DAP or VCM plus β-lactams with DAP or VCM monotherapy demonstrated no significant decrease in mortality in patients treated with the combination therapy [14–17].

The mechanisms underlying the DAP antimicrobial activity include cell wall synthesis inhibition and cell membrane targeting [30,

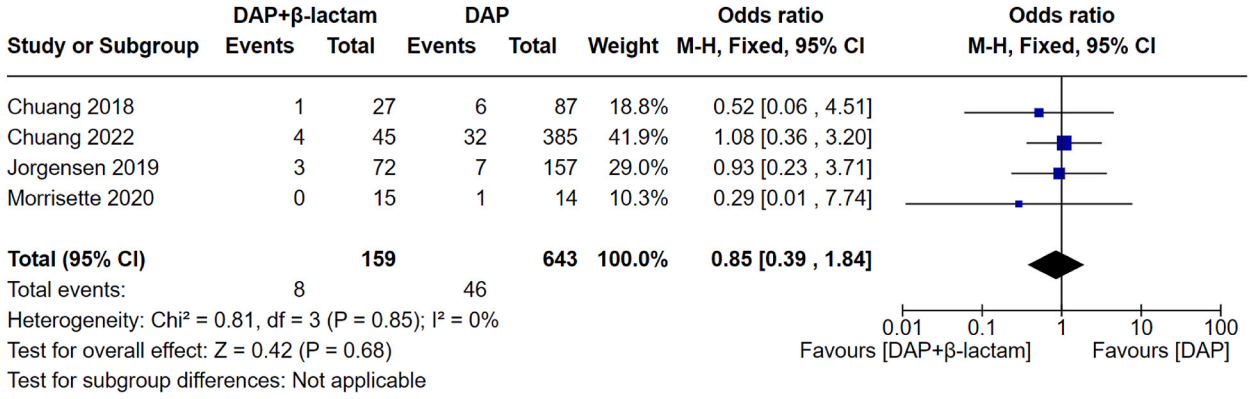

Fig. 4. Forest plot of the odds ratio for CPK elevation between patients treated with DAP pus β-lactams or DAP monotherapy. This figure meta-analyzed CPK elevation between patients treated with DAP pus β-lactams or DAP monotherapy.

31]. *In vitro* studies have demonstrated the synergistic effects of β-lactams against MRSA and VRE by adding β-lactams to DAP monotherapy [32–35]. β-lactams induce alterations in at least three major cell envelope phenotypes such as surface charge, membrane fluidity, and cardiolipin content, strengthening a bond with the cell membrane of DAP [36,37]. Moreover, although exposure to DAP causes elevated MIC during the treatment [38], a combination of β-lactam prevents an increase in the MIC of DAP [39]. Therefore, multiple effects based on these basic studies could improve clinical outcomes in patients with BSI due to MRSA and VRE.

Our meta-analysis included two studies on DAP plus ceftaroline, which has bactericidal activity, as a combination therapy against BSI due to MRSA [25,27]. The mortality of patients with BSI due to MRSA reported in these studies demonstrated no statistically significant reduction in mortality. In contrast, the other two studies [24,28] indicated that DAP plus β-lactams therapy, except for ceftaroline, significantly decreased clinical failure. These results indicated that the improvement in the antimicrobial activity of DAP was more influential than the additive effect of the antimicrobial activity. The subgroup analysis revealed that a combination of DAP and β-lactams therapy demonstrated advantages over DAP monotherapy for mortality of BSI due to MRSA or VRE; however, it was not statistically significant. The number of cases of MRSA bacteremia alone may not be sufficient for analysis because of the small number of cases reported in each report. As mentioned above, basic studies have been conducted to demonstrate a certain level of efficacy, and future analyses are expected. In addition to VRE as well MRSA, a combination of DAP and β-lactams has been reported to exert synergistic effects [40]. In contrast, DAP requires a dose of 9 mg/kg or more to demonstrate clinical benefits in combination with β-lactams against BSI due to VRE [23]. The reports used in this analysis did not adequately meet that dosage, which could be a reason why statistical significance could not be demonstrated.

Our meta-analysis indicated that compared with the DAP monotherapy, combination therapy of DAP with β-lactams did not increase CPK elevation. It has been reported that increased DAP dosage increases the risk of CPK elevation [41]. However, the DAP dose was >6 mg/kg in studies included in our meta-analysis. Risk factors reported for elevated CPK following DAP administration include trough concentration of DAP, use of statins or antihistamines, body mass index of 30 kg/m^2 or more, African American, and history of rhabdomyolysis, not including concomitant use of β-lactam drugs [42–44]. It was further emphasized that CPK elevation due to β-lactams is not a major side effect [45]. None of the studies included in this meta-analysis found any differences in the patient background for these risk factors, with BMI not exceeding 30 kg/m^2 in the combination and monotherapy groups.

Despite the higher cost of DAP compared to VCM, its cost-effectiveness for BSI has been reported to be comparable ($23,639 vs. $25,668) against BSI due to MRSA (with or without endocarditis) [46]. Our results suggest that the combination of DAP and β-lactam could have superior therapeutic efficacy and cost-effectiveness.

Our meta-analysis had several limitations. First, all studies included in our meta-analysis were retrospective, and only six studies were included. Second, due to the insufficient number of reports, we were unable to perform an analysis adjusting for background factors regarding patient background, severity of illness, dose of DAP, type of beta-lactam medication, and cause of disease that can affect mortality. Hence the generalizability and robustness could not be guaranteed, it is clear that the heterogeneity is small. Furthermore, the definition of clinical failure could not be clearly categorized due to the background of insufficient number of reports. Third, we evaluated the adverse events associated with CPK elevation, a characteristic side effect of DAP, and one of the factors contributing to treatment discontinuation. Due to the diversity of adverse events observed in each study (e.g., acute kidney injury, thrombocytopenia, *Clostridioides difficile* infection), only CPK elevation was evaluated. In addition, specific values, such as the normal range of CPK values, were not defined and may vary from each report. Possible drug rashes and allergic symptoms that could occur with the addition of β-lactams have not been studied. However, further studies are required to evaluate these factors.

6. Conclusion

In conclusion, our meta-analysis demonstrated that the combination therapy of DAP and β-lactams could improve the prognosis for patients with BSI due to GPC, compared with DAP monotherapy. Combination therapy can be considered as an option for the empirical treatment of suspected BSI due to GPC.

Data availability statement

This manuscript has not been registered in any repository.
Data will be made available on request.

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Ethical approval and consent to participate

Not required.

CRediT authorship contribution statement

Takumi Umemura: Writing – original draft, Investigation, Formal analysis, Data curation. **Hideo Kato:** Writing – review & editing, Investigation, Formal analysis, Conceptualization. **Nobuhiro Asai:** Writing – review & editing. **Mao Hagihara:** Writing –

review & editing. **Jun Hirai:** Writing – review & editing. **Yuka Yamagishi:** Writing – review & editing. **Hiroshige Mikamo:** Writing – review & editing, Supervision, Project administration, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Hiroshige Mikamo reports a relationship with Department of Clinical Infectious Diseases, Aichi Medical University that includes: funding grants. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2024.e29811.

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